Universidade Estadual de Campinas
Faculdade de Odontologia de Piracicaba

Luiz Carlos do Carmo Filho

INFLUÊNCIA DA MACROGEOMETRIA DE IMPLANTES DENTÁRIOS DURANTE O PROCESSO DE CICATRIZAÇÃO: UM ESTUDO CLÍNICO, PROSPECTIVO, RANDOMIZADO DE BOCA DIVIDIDA

THE EFFECT OF IMPLANT MACROGEOMETRY ON IMPLANT STABILITY AND BIOMECHANICS: A RANDOMIZED, CONTROLLED, SPLIT-MOUTH CLINICAL STUDY

Piracicaba

2017

Luiz Carlos do Carmo Filho

INFLUÊNCIA DA MACROGEOMETRIA DE IMPLANTES DENTÁRIOS DURANTE O PROCESSO DE CICATRIZAÇÃO: UM ESTUDO CLÍNICO, PROSPECTIVO, RANDOMIZADO DE BOCA DIVIDIDA

THE EFFECT OF IMPLANT MACROGEOMETRY ON IMPLANT STABILITY AND BIOMECHANICS: A RANDOMIZED, CONTROLLED, SPLIT-MOUTH CLINICAL STUDY

Tese apresentada à Faculdade de Odontologia de Piracicaba da Universidade Estadual de Campinas como parte dos requisitos exigidos para a obtenção do título de Doutor em Clínica Odontológica, área de concentração em Prótese Dental

Thesis presented to the Piracicaba Dental School of the University of Campinas in partial fulfillment of the requirements for the degree of Doctor in Dental Clinic, in Dental Prosthesis area

Orientadora: Altair Antoninha Del Bel Cury

Este exemplar corresponde a versão final da tese defendida pelo aluno Luiz Carlos do Carmo Filho e orientada pela Profa. Dra. Altair Antoninha Del Bel Cury

Piracicaba

2017

Agência(s) de fomento e nº(s) de processo(s): Não se aplica.

Ficha catalográfica
Universidade Estadual de Campinas
Biblioteca da Faculdade de Odontologia de Piracicaba
Marilene Girello - CRB 8/6159

C213i

Carmo Filho, Luiz Carlos do, 1978-
Influência da macrogeometria de implantes dentários durante o processo de cicatrização : um estudo clínico, prospectivo, randomizado de boca dividida / Luiz Carlos do Carmo Filho. – Piracicaba, SP : [s.n.], 2017.

Orientador: Altair Antoninha Del Bel Cury.
Tese (doutorado) – Universidade Estadual de Campinas, Faculdade de Odontologia de Piracicaba.

1. Implantes dentários. I. Del Bel Cury, Altair Antoninha,1948-. II. Universidade Estadual de Campinas. Faculdade de Odontologia de Piracicaba. III. Título.

Informações para Biblioteca Digital

Título em outro idioma: The effect of implant macrogeometry on implant stability and biomechanics : a randomized, controlled, split-mouth clinical study
Palavras-chave em inglês:
Dental implants
Área de concentração: Prótese Dental
Titulação: Doutor em Clínica Odontológica
Banca examinadora:
Altair Antoninha Del Bel Cury [Orientador]
Fernanda Faot
Thais Marques Simek Vega Gonçalves
Manoel Martin Junior
Antônio Pedro Ricomini Filho
Data de defesa: 06-03-2017
Programa de Pós-Graduação: Clínica Odontológica

UNIVERSIDADE ESTADUAL DE CAMPINAS
Faculdade de Odontologia de Piracicaba

A Comissão Julgadora dos trabalhos de Defesa de Tese de Doutorado, em sessão pública realizada em 06 de Março de 2017, considerou o candidato LUIZ CARLOS DO CARMO FILHO aprovado.

PROFª. DRª. ALTAIR ANTONINHA DEL BEL CURY

PROFª. DRª. FERNANDA FAOT

PROFª. DRª. THAIS MARQUES SIMEK VEGA GONÇALVES

PROF. DR. MANOEL MARTIN JUNIOR

PROF. DR. ANTÔNIO PEDRO RICOMINI FILHO

A Ata da defesa com as respectivas assinaturas dos membros encontra-se no processo de vida acadêmica do aluno.

DEDICATÓRIA

À minha amada esposa Anna, pelo amor e apoio incondicional em todos os momentos, principalmente nos de incerteza, ansiedade, estresse e cansaço, que fizeram parte desta caminhada. As minhas filhas, Marina e Lívia, pelo amor e carinho que recarregavam as minhas energias a cada retorno. Sem vocês nada faria sentido.

Aos meus pais, Luiz Carlos e Roseli, por tudo que fizeram e passaram para formar os filhos e pelo exemplo de pessoas que são, amo muito vocês.

Aos meus irmãos, Fernando, Vitor e Felipe, minhas cunhadas Luana, Isabelle e Ácea pela amizade e companherismo de todas as horas.

E a toda a minha família e amigos que souberam entender a minha ausência nos muitos momentos desde que ingressei no doutorado.

AGRADECIMENTOS ESPECIAIS

Á Profa. Dra. Altair Antoninha Del Bel Cury, minha brilhante orientadora, a qual sou grato por ter acreditado e investido em mim. O seu exemplo como professora e mentora me inspiraram durante esses 4 anos que tive o previlégio de ser seu orientado.

A minha mentora Profa. Dra. Fernanda Faot, pela amizade e confiança em meu trabalho. Seus brilhantes ensinamentos, conselhos pessoais e profissionais desde que nos conhecemos me tornou uma pessoa e um profissional melhor. Espero poder um dia retribuir toda a sua dedicação á nossa amizade e a parceria na execução deste trabalho.

AGRADECIMENTOS

À Deus, pela vida e pela possibilidade de poder aprender e evoluir, com pessoas especiais que fazem parte da minha caminhada.

À Universidade Estadual de Campinas por meio do seu magnífico Reitor, Prof. Dr. José Tadeu.

À Faculdade de Odontologia de Piracicaba da Universidade Estadual de Campinas, na pessoa de seu Diretor, Prof. Dr. Guilherme Elias Pessanha Henriques.

À Coordenadora dos Cursos de Pós-Graduação da Faculdade de Odontologia de Piracicaba, Profa. Dra. Cínthia Pereira Machado Tabchoury.

À Coordenadora do Programa de Pós-Graduação em Clínica Odontológica da Faculdade de Odontologia de Piracicaba, Prof. Dra. Karina Gonzales Silvério Ruiz.

À Universidade Federal de Pelotas, por meio do seu magnífico Reitor Prof. Dr Pedro Rodrigues Curi Hallal.

A empresa Signo Vinces por meio do seu proprietário Fredy Vogt pelo apoio e disponibilidade para o projeto. Aos Engenheiros Andreas Firzlaff e Paulo Martini que não mediram esforços para a realização deste projeto.

Aos Professores da Área de Prótese Parcial Removível, Profa. Dra. Célia R. Barbosa, Prof. Dra. Renata C. M. R. Garcia, em especial ao amigo Prof. Dr. Wander J. da Silva pelo conhecimento compartilhado, boa convivência, carinho e atenção.

À Sra. Gislaine Piton, técnica do Laboratório de Prótese Parcial Removível, obrigada pela ajuda, atenção durante os anos de convivência.

À equipe da Coordenadoria Geral dos Programas de Pós-Graduação da Faculdade de Odontologia de Piracicaba, Ana P. Carone, Claudinéia P. Pradella, Érica A. P. Sinhoreti, Leandro Viganó, Raquel Q. Marcondes Cesar.

A todos amigos e colegas de pós-graduação pela convivência agradável. Em especial agradeço aos amigos, Dimorvan Bordin, Marco Aurélio Carvalho, Tales Candido, Camila Lima Andrade, Livia Forster, Raissa Machado, Indira

Cavalcanti, Cindy Goes Dodo, Paula Bavia, Marcele Pimentel Jardim, Giselle Ribeiro, Thaís Gonçalves, Victor Munhoz, Giancarlo de La Torre Canales, Vinícius Santos e Edmara Tatiely Bergamo.

Em especial agradeço a Marina Madruga, pela dedicação, auxílio e amizade durante o estudo. Á equipe da Madruga & Vilela Odontologia, Juliana, Andressa, Rose e Renato Vilela por todo apoio e tempo dedicados durante a realização do estudo.

Á equipe do Carmo Dental Institute, em especial a Julie Felix que sempre esteve pronta para me auxiliar.

RESUMO

O presente trabalho avaliou clinicamente a influência de diferentes macrogeometrias com diferentes protocolos de fresagem de implantes dentais na resposta biológica dos tecidos peri-implantares monitorando os parâmetros clínicos, a estabilidade secundária e descrevendo o índice de sucesso. De acordo com os critérios de inclusão e exclusão, 23 voluntários desdentados bilaterais na região posterior de mandíbula foram selecionados para fazer parte deste estudo clinico estudo clínico, prospectivo, randomizado de boca dividida. Os dados referentes a classificação da qualidade óssea, altura cortical, espessura cortical lingual, espessura cortical vestibular, altura média, espessura média, altura total, espessura total foram coletados previamente a cirurgia de instalação dos implantes. Cada voluntário recebeu pelo menos 4 implantes de cada macrogeometria, a geometria padrão, Integra (IN) e 3 geometrias que induzem a “câmara coágulo”: Duo (D), Compact (C) and Infra (IF). As variáveis de desfecho do estudo foram torque de inserção (TI), estabilidade primária (EP) e secundária do implante (ES) e parâmetros clínicos relacionados a saúde peri-implantar. O torque de inserção no momento da instalação (T0) foi registrado, bem como o coeficiente de estabilidade do implante (ISQ). Dados relacionados a ES, índice de placa visível (IPV), inflamação peri-implantar (IP) e presença de cálculo (PC) foram coletadas após 07, 14, 21, 42, 60 e 90 dias. TI, EP e ES, IPV, IP e PC foram comparadas utilizando ANOVA ou ANOVA-R seguido de Teste de Tukey-Kramer. O teste de correlação de Spearman foi realizado para investigar as seguintes associações entre: i) características ósseas e mecânicas (TI x EP), ii) tipo ósseo e tipo de implante, iii) TI e ISQ em todas as fases. Todas as análises foram consideradas significantes ao nível de 5%. A macrogeometria não foi um fator significante nos valores de TI e ISQ. O período 7dias foi considerado o mais crítico para a obtenção da ES (p=0,0001). IPV foi influenciado pelos períodos de cicatrização e pela interação entre fase e macrogeometria do implante (p=0,0001; p=0,0328) com escores significativos mais altos para os implantes D e IN somente após 7 dias. IP somente foi influenciada pela fase de cicatrização (p=0,0001) mostrando um decréscimo significativo desde o tempo de 7 (1,07±0,89) até 21 dias (0,18±0,18). Associação positiva significativa foi observada entre o torque de inserção e altura total do leito ósseo (r=0,2504; p=0,0149) e espessura da cortical lingual (r=0,2621; p=0,0107). Diferentemente, associação significativa inversa foi encontrada entre TI e espessura medular (r= -0,2193; p=0,0337), EP e espessura total do leito ósseo (r=-0,2865; p=0,0054) e, EP espessura da cortical vestibular(r=-0,2227; p=0,0319). A associação mais significante entre TI e valores de ISQ foi observada para o implante D na fase de

90 dias (r=0,5964; p=0,0027). Considerando as limitações deste estudo, conclui-se que a macrogeometria não influenciou os valores de TI e ISQ, sendo o período entre 7 e 14 dias o mais crítico para o monitoramento do sucesso da cicatrização. A relação entre TI e ISQ mostrou-se mais evidente para o implante Duo apenas no intervalo final da cicatrização.
Palavras-chave: implante dental; macrogeometria; estabilidade primária, estabilidade secundária, torque de inserção.

ABSTRACT

This study assessed the influence of four implant macrogeometries on bone properties and peri-implant health parameters during the healing process. Ninety-nine implants were placed bilaterally in posterior mandibles of 23 patients. Each patient received at least 4 unique dental implant macrogeometries: the standard geometry Integra (IN) and three geometries that induce a 'healing chamber': Duo (D), Compact (C) and Infra (IF). The insertion torque (IT) and the implant stability quotient (ISQ) were measured as a proxy for the primary or secondary stability (PS and SS, respectively). In addition, three clinical parameters related to the peri-implant health were monitored: the visible plaque index (VPI), the peri-implant inflammation (PI) and the presence of calculus (CC). The data were collected after 7, 14, 21, 42, 60 and 90 days. The outcome variables were compared using one-way ANOVAs and repeated measures ANOVAs or ANOVA-R followed by the Turkey-Kramer test. The Spearman correlation test was performed to investigate the associations between: i) bone and mechanical characteristics (IT x PS), ii) bone type and type of implant, iii) IT and ISQ for all time intervals. All analyses were considered significant at the 5% level. Macrogeometry did not significantly influence IT and ISQ values. The minimum ISQ was recorded after 7 days ($p = 0.0001$). An intermediate ISQ was found after 14 days, where the ISQ reached values that are statistically identical to the primary stability. The VPI was influenced by the healing time ($p = 0.0001$) and by the interaction between time and implant macrogeometry ($p = 0.0328$), with significantly higher scores for the D and IN implants after 7 days. The PI was only influenced by the healing time ($p = 0.0001$), and showed a significant decrease from the time of 7 (1.07 ± 0.89) to 21 days (0.18 ± 0.18). A significant positive correlation was observed between IT and total bone height ($r = 0.2504$; $p = 0.0149$) and between IT and lingual cortical width ($r = 0.2621$; $p = 0.0107$). Conversely, IT and medullary thickness ($r = -0.2193$, $p = 0.0337$), total bone width ($r = -0.2865$; $p = 0.0054$) and buccal cortical width ($r = -0.22227$, $p = 0.0319$) were negatively correlated. The most significant correlation between IT and SS values was recorded by D implants after 90 days ($r = 0.5964$; $p = 0.0027$). Within the limitations of this study, it can be concluded that macrogeometry did not influence IT nor ISQ values. Minimum stability was observed after 7 days, and the secondary stability started between 7 and 14 days. The relationship between IT and SS was more evident for the Duo implant, but only in the final stage of healing process (90 days).

Key-words: dental implants; macrogeometry, insertion torque, primary stability, secondary stability

SUMÁRIO

INTRODUÇÃO

A cicatrização do leito cirúrgico após a instalação de implantes dentais é baseada na osseointegração ou “anquilose funcional” (Branemark et al., 1969; Schroeder et al., 1976) documentada através do estabelecimento histológico de contato direto entre osso-implante. A competência biomecânica desta interface é basicamente determinada por i) inserção cirúrgica do implante com mínimo trauma, ii) estabilidade primária e iii) controle da infecção e micromovimentação durante a cicatrização (Berglundh et al., 2003).

A compreensão biológica da osseointegração tem sido por décadas considerada como uma sequência de eventos que ocorrem no processo alveolar após a instalação de implantes, incluindo a necrose tecidual e a subsequente reabsorção do tecido ósseo traumatizado ao redor do corpo do implante concomitante, com a neoformação óssea. A descrição destes eventos para a determinação da taxa de osseointegração foi baseada primeiramente na interpretação de eventos histológicos em modelos animais, com foco na descrição da magnitude do efeito de compressão óssea, traduzido pela intensidade da necrose tecidual observada na interface de contato osso-implante (Berglundh et al., 2003).

Somente no ano de 2010, Lang e colaboradores (Lang et al., 2011), em um estudo em humanos, descreveram os eventos histológicos locais de reabsorção e aposição, relacionados a cicatrização precoce do implante. Nesse estudo, os resultados não diferenciaram a cinética da osseointegração entre implantes de superfície hidrofóbica e hidrofílicas entre 7 e 42 dias. Entretanto, após 2 e 4 semanas, diferenças relacionados ao grau de osseointegração puderam ser descritas para estas diferentes superfícies.

Atualmente, uma nova visão da osseointegração de implantes dentais, baseada na osteoimunologia, vem sendo descrita por mecanismos biológicos controlados pelo sistema imunológico, permitindo que a sequência de eventos inflamatórios precoces que ocorrem durante a cicatrização, possa explicar como a interação celular na superfície de um implante pode predizer os comportamentos de sobrevivência, crescimento e diferenciação celular (Trindade et al., 2016). Este conceito, abre um grande campo a ser explorado na descrição da cascata de eventos, em nível celular, da osseointegração por meio de metodologias não invasivas e técnicas de analises modernas e eficientes de quantificação de biomarcadores da inflamação, metabolismo e remodelação óssea, contribuindo para detalhar e compreender achados descritos em estudos clássicos baseados em biópsias do tecido ósseo (Terheyden et al., 2012; Nishimura, 2013; Shanbhag et al., 2015).

A constante evolução dos implantes dentários, em especial em relação ao desenvolvimento de novas superfícies permitiu um intervalo de tempo diminuído entre a instalação cirúrgica e o carregamento funcional (De Bruyn et al., 2008; Vandeweghe et al., 2013) além da melhora significativa do índice de sucesso da osseointegração. Entretanto, a diminuição do intervalo de carregamento não está somente relacionado à modificação da superfície, mas também a uma série de parâmetros envolvidos no projeto dos implantes como: a macrogeometria, o formato das roscas, o protocolo de fresagem (Coelho et al., 2015) e a conexão protética (Torcato et al., 2016). Neste sentido, apesar de um grande número de estudos *in vivo* estarem disponíveis na literatura, a maioria dos parâmetros envolvidos na obtenção de rápida osseointegração e de longevidade ainda necessitam de evolução e precisam ser melhor explorados (Jimbo et al., 2014; Coelho et al., 2015). A dificuldade na avaliação dos sistemas de implante ainda reside na falta de uma abordagem sistemática da cascata de cicatrização óssea em relação ao implante. A ausência de uma abordagem sequencial e objetiva quanto aos parâmetros a serem avaliados, tais como, macrogeometria, microgeometria, nanogeometria e instrumentação cirúrgica, em ensaios laboratoriais, pré-clínicos e clínicos dificultam a análise dos resultados por parte dos pesquisadores e clínicos. (Gottlow et al., 2012; Coelho & Jimbo, 2014).

Os efeitos da macrogeometria e a dimensão da instrumentação cirúrgica na diminuição do período de osseointegração (Leonard et al., 2009; Freitas eel al., 2012) ainda são tópicos pouco explorados do ponto de vista clinico. A maioria dos estudos tem sido desenvolvido em modelos animais (Marin et al., 2010; Coelho et al., 2011) que têm explorado os mecanismos biológicos envolvidos em implantes com diferentes macrogeometrias e protocolos de fresagem óssea. No que se refere ainda a macrogeometria e a instrumentação cirúrgica, estes sempre visaram aumentar de forma significativa a estabilidade inicial entre osso e implante, entretanto essa interação só contempla fatores mecânicos sem repercutir em qualquer modificação na interação biológica, que ocorre somente quando a osseocondução se inicia (estabilidade secundária) (Norton, 2013; Chowdhary et al., 2013). O travamento mecânico, clinicamente observado pelo torque de inserção, é influenciado pela macrogeometria, microtopografia associados aos protocolos de osteotomia, pois regulam a tensão e o atrito na interface osso-implante (Petrie et al., 2005; Isidor, 2006; Huang et al., 2011; Gottlow et al., 2012, Chowdhary et al., 2013). Altos torques de inserção resultam em maior estabilidade primária, e esta tem sido determinante do tipo de carregamento imediato ou convencional do implante.

Este conceito baseia-se no fato de que o tecido ósseo é um material elástico e que a tensão e a estabilidade terão uma relação linear e se manterá igual durante o período de cicatrização (Halldin et al., 2011). No entanto, a estabilidade do implante diminui durante o período de remodelação óssea, em resposta ao trauma sofrido. Essa diminuição da estabilidade depende de fatores como a fresagem do osso e da compressão do tecido no momento da instalação do implante, que quando alta pode ocasionar excessivas microfissuras podendo causar fraturas (Donahue & Galley, 2006; Chapurlat & Delmas, 2009; Shemtov-Yona & Rittel 2015). Essa compressão excessiva pode causar necrose do tecido ósseo ao redor do implante devido à isquemia causada nos capilares, resultando em maior reabsorção óssea (Bashutsli et al., 2009). Tanto as microfissuras como a compressão tecidual, são observadas em diferentes graus quando existe uma incompatibilidade do diâmetro exterior da rosca do implante com o diâmetro interno da instrumentação cirúrgica (Marin et al., 2010; Coelho et al., 2011).

Desta forma, diferentes graus de fricção e atrito entre implante e osso podem ser observados, conduzindo a maiores ou menores torques de inserção. Porém, evidencias mostram que o torque de inserção pode não ser proporcional a estabilidade primária, e ainda com o estabelecimento do processo de reparo ósseo, o implante pode alcançar resistência a micromovimentação, mesmo sob carga funcional (Jimbo et al., 2014). Altos torques de inserção apesar de questionados do ponto de vista clínico (Li et al., 2015; Wang et al., 2015), ainda resultam em tensão excessiva e diminuição da estabilidade secundária, provocando respostas biológicas negativas (essa resposta óssea é mediada pela reabsorção tecidual nativa e posterior aposição óssea na parede do implante), e este processo também pode ser atribuído ao desenho das roscas e ao protocolo de fresagem (Raghavendra et al., 2005).

A evolução desse quadro foi a releitura de conceitos até então tidos como ideais. O primeiro conceito a ser revisitado, foi o da justaposição total do implante em relação ao leito ósseo (Berglundh et al., 2003; Lang et al., 2011). Os protocolos de fresagem do tecido ósseo quando associados à macrogeometrias diferenciadas resultam em espaços entre o leito cirúrgico e o implante (Leonard et al., 2009; Marin et al., 2010; Freitas et al., 2012; Coelho & Jimbo, 2014; Jimbo et al., 2014). Estes espaços vazios criados entre o osso e o corpo do implante, são referidos como "câmara de coágulo" ou "câmaras de cicatrização", as quais são preenchidas pelo coágulo sanguíneo imediatamente após a instalação do implante. Esta condição biológica não contribui para a estabilidade primária, porém é considerado um fator chave para a estabilidade secundária (biológica). A forma que a cicatrização acontece dentro da câmara de coágulo, quanto ao tamanho que esta deve ter para contemplar tanto a estabilidade primária quanto a secundária estão sendo bastante discutidas na literatura (Marin et al., 2010; Coelho et al., 2010; Coelho et al., 2011). O consenso é que a formação óssea se dá pela ossificação intramenbranosa, promovendo a formação de osso novo diretamente sobre a superfície do implante, inibindo ou reduzindo drasticamente o processo de ossificação aposicional, que necessita da remoção do tecido ósseo necrótico para a posterior formação de tecido novo (Coelho & Jimbo, 2014).

Embora os implantes com macrogeometria que favoreçam a câmara de coágulo tenham uma estabilidade primaria menor que os implantes com formação óssea aposicional, eles alcançam a estabilidade primária (baixa micromovimentação) favorável para permitir o desenvolvimento ósseo na interface osso-implante. Estudos recentes (Leonard et al., 2009; Coelho et al., 2010; Coelho et al., 2011; Jimbo et al., 2014; Coelho et al., 2015a; Coelho et al., 2015b), porém em sua maioria modelos animais, tem investigado a influência das características desta nova proposta de macrogeometria para implantes, no que se refere ao formato de rosca, passo, profundidade, altura de rosca, ângulo de face da rosca, protocolos de osteotomias, torque inicial, estabilidade primária e secundária assim como a manutenção da osseointegração. O entendimento desses fatores e aplicação deles de uma forma apropriada pode auxiliar na redução de insucessos e no aumento do desempenho clínico dos implantes.

Tanto a presença de micro-roscas na porção cervical, assim como o formato do corpo do implante podem influenciar a resposta inflamatória do tecido ósseo no processo de osseointegração porque norteiam os protocolos cirúrgicos de instalação dos implantes, podendo, desta maneira, propiciar uma resposta inflamatória de maior ou menor amplitude e interferindo diretamente na fase de cicatrização do leito ósseo. Para observar este fenômeno e comprovar o benefício biológico da presença da micro-rosca na porção cervical de implantes de formatos distintos e ainda conexões protéticas diferentes, estudos clínicos longitudinais que englobem desde a fase de osseointegração até a reabilitação definitiva precisam ser executados. Estudos clínicos atuais, apesar de relatarem a reabsorção óssea esperada e aceitável, apenas tem se baseado na contaminação bacteriana local para explicar os resultados obtidos, sem coletar ou avaliar dados relacionados especificamente ao leito ósseo, protocolos de fresagem cirúrgica e macrogeometria do implante (Quian et al., 2012).

Assim, no presente estudo, o objetivo foi comparar o comportamento biológico e biomecânico de implantes com macrogeometrias e protocolos de fresagem distintos e demonstrar a influência dos mesmos na resistência da interface osso-implante e na integridade do tecido per-implantar durante a fase de cicatrização. Adicionalmente, a influência da proporção de osso cortical e medular e critérios de saúde peri-implantar nos desfechos clínicos durante o período de osseointegração foram investigados.

2 ARTIGO

The effect of implant macrogeometry on peri-implant healing outcomes: a randomized, controlled, split-mouth clinical study.

Luiz Carlos do Carmo Filho[1], Fernanda Faot[2], Dimorvan Bordin[1], Marina Matos Madruga[3], Altair Antoninha Del Bel Cury[4]

[1] MSc PhD student, Department of Prosthodontics and Periodontology Piracicaba Dental School, University of Campinas, Piracicaba, Brazil
[2] Professor, Department of Restorative Dentistry, School of Dentistry, Federal University of Pelotas, Brazil
[3] MSc, PhD student, Graduate Program in Dentistry, Federal University of Pelotas, Pelotas, RS, Brazil
[4] Professor, Department of Prosthodontics and Periodontology Piracicaba Dental School, University of Campinas, Piracicaba, Brazil

*Corresponding author:
Profa. Dra. Altair A. Del Bel Cury, Piracicaba Dental School, University of Campinas. Address: Limeira Avenue 901,

13414-903, Piracicaba, SP, Brazil
e-mail: altair@unicamp.br

The authors declare no potential conflicts of interest with regard to the authorship and / or publication of this article.

Author Contribution Statement: Conceived and designed the experiments: AC, FF, LC Performed the experiments: LC, FF, MM, DB. Data analysis/interpretation: LC, FF, DB, MM, DB, AC. Drafting and critical revision of article: LC, FF, DB, MM, DB, AC. Approval of article: LC, FF, DB, MM, DB, AC.

Abstract

This study assessed the influence of four implant macrogeometries on bone properties and peri-implant health parameters during the healing process. Ninety-nine implants were placed bilaterally in posterior mandibles of 23 patients. Each patient received at least 4 unique dental implant macrogeometries: the standard geometry Integra (IN) and three geometries that induce a 'healing chamber': Duo (D), Compact (C) and Infra (IF). The insertion torque (IT) and the implant stability quotient (ISQ) were measured as a proxy for the primary or secondary stability (PS and SS, respectively). In addition, three clinical parameters related to the peri-implant health were monitored: the visible plaque index (VPI), the peri-implant inflammation (PI) and the presence of calculus (CC). The data were collected after 7, 14, 21, 42, 60 and 90 days. The outcome variables were compared using one-way ANOVAs and repeated measures ANOVAs or ANOVA-R followed by the Turkey-Kramer test. The Spearman correlation test was performed to investigate the associations between: i) bone and mechanical characteristics (IT x PS), ii) bone type and type of implant, iii) IT and ISQ for all time intervals. All analyses were considered significant at the 5% level. Macrogeometry did not significantly influence IT and ISQ values. The minimum ISQ was recorded after 7 days ($p = 0.0001$). An intermediate ISQ was found after 14 days, where the ISQ reached values that are statistically identical to the primary stability. The VPI was influenced by the healing time ($p = 0.0001$) and by the interaction between time and implant macrogeometry ($p = 0.0328$), with significantly higher scores for the D and IN implants after 7 days. The PI was only influenced by the healing time ($p = 0.0001$), and showed a significant decrease from the time of 7 (1.07 ± 0.89) to 21 days (0.18 ± 0.18). A significant positive correlation was observed between IT and total bone height ($r = 0.2504$; $p = 0.0149$) and between IT and lingual cortical width ($r = 0.2621$; $p = 0.0107$). Conversely, IT and medullary thickness ($r = -0.2193$, $p = 0.0337$), total bone width ($r = -0.2865$; $p = 0.0054$) and buccal cortical width ($r = -0.22227$, $p = 0.0319$) were negatively correlated. The most significant correlation between IT and SS values was recorded by D implants after 90 days ($r = 0.5964$; $p = 0.0027$). Within the limitations of this study, it can be concluded that macrogeometry did not influence IT nor ISQ values. Minimum stability was observed after 7 days, and the secondary stability started between 7 and 14 days. The relationship between IT and SS was more evident for the Duo implant, but only in the final stage of healing process (90 days).

1. Introduction

The healing of bone bed after dental implants installation relies on the achievement of the osseointegration process or "functional ankylosis" (Branemark et al., 1969; Schroeder et al., 1976). This biological process results in the histological establishment of direct bone-implant contact. The biomechanical competence of this bone-implant interface is determined by i) the trauma during surgical insertion of the implant, ii) establishment of primary stability, and iii) infection control and micro-movement during healing (Berglundh et al., 2003).

The development of new implant surfaces has allowed a shorter time interval between surgical installation and functional loading (Le Guéhennec et al., 2007; Smeets et al., 2016; Doornewaard et a., 2016) improving the success rate of osseointegration, significantly. However, the decrease in loading interval is not only related to the surface modification, but also to a series of parameters related to implant design such as: implant macrogeometry, thread size, drilling protocol (Coelho et al., 2015) and prosthetic connection (Torcato et al., 2016). Although *in vivo* studies are available (Jimbo et al., 2014; Coelho et al., 2015), most of the parameters involved in achieving rapid osseointegration and longevity still need to be explored in more detail, to enable the design of dental implants that remain stable for years. Thus, aspects related to macro-, micro- and nanogeometry and surgical instrumentation have been widely discussed mainly focused on the biological stability of bone-implant interface that is undergoing active remodeling during osseointegration, both at the cortical and medular bone levels (McCullough & Klokkevold, 2016)

Clinically, the effects of macrogeometry and bone drilling protocols in the period of osseointegration are still unexplored topics. Most studies focused on animal models that explored the biological mechanisms involved in the healing process with different macrogeometries and bone drilling protocols (Leonard et al., 2009; Freitas et al., 2012). As far as implant macrogeometry and surgical instrumentation are concerned, these have always been aimed to increase the initial stability between bone and implant. However, the primary stability only deals with the initial mechanical factors without considering the subsequent biological responses, which start at the beginning of osseoinduction and determine the secondary stability (Norton et al., 2013; Chowdhary et al., 2013).

The mechanical locking is influenced by macrogeometry, microtopography associated with osteotomy protocols, as they regulate tension and friction at the bone-implant interface (Petrie & Willians 2005; Isidor, 206; Huang et al., 2011; Gottlow et al., 2012; Chowdhary et al., 2013), and is clinically measured by the insertion torque. So, it is expected that high insertion torques result in greater primary stability, and this determined the loading protocol of the implants. However, it is also well known that insertion torque may not be proportional to primary stability (Santamaría-Arrieta et al., 2016). Even with the establishment of the bone repair process, the implant can achieve resistance to micromovement, even under a functional load (Jimbo et al., 2014). High insertion torques are clinically questioned (Li et al., 2015; Wang et al., 2015), and can result in excessive tension and decrease of secondary stability, provoking negative biological responses that can also be exasperated by thread design and drilling protocol (Raghavendra et al., 2005; Barone et al., 2016).

The necessity to obtain total juxtaposition of the implant and the bone bed has been questioned, although it was previously considered ideal for osseointegration (Berglundh et al., 2003; Lang et al., 2011). New bone drilling protocols associated with certain implant macrogeometries result in spaces between the surgical bed and the implant (Leonard et al., 2009; Marin et al., 2010; Freitas et al., 2012; Coelho & Jimbo, 2014; Jimbo et al., 2014). These "clot chambers" or "healing chambers" are filled by the blood clot immediately after installation of the implant. This biological condition does not contribute to primary stability, but is considered a key factor for secondary (biological) stability. The nature of the healing process inside the clot chamber, and the optimal to promote both primary and secondary stability are topics of intense discussion in literature (Marin et al., 2010; Coelho et al., 2010; Coelho et al., 2011). The consensus is that bone formation occurs by intramembranous ossification, promoting the new bone formation directly on the surface of the implant. The latter drastically reduces appositional ossification, which necessitates the removal of the necrotic bone tissue for subsequent new tissue formation (Coelho & Jimbo, 2014).

Although implants with macrogeometries that favor the formation of a healing chamber have lower primary stability than implants that trigger appositional bone formation, they achieve sufficient primary stability to allow bone formation at the bone-implant interface. Studies using animal models (Leonard et al., 2009; Coelho et al., 2010; Coelho et al., 2011; Jimbo et al., 2014; Coelho et al., 2015a; Coelho et al., 2015b) have investigated the biological influences on osseointegration for these new implant macrogeometries. These studies focused on thread changes (size, pitch, depth, height, face angle) osteotomy protocols, initial torque, primary and secondary stability and the maintenance of osseointegration. Understanding these factors and the relationships between them will allow them to be widely used clinically, according to specific indications based on bone site characteristics and properties. Precise recommendations could help to reduce failures and to increase the clinical performance of these implants over time.

This study compared the biomechanical and biological behavior of implants with 4 different macrogeometries and different drilling protocols. Their influence on bone resistance, bone-implant interface stability and peri-implant health parameters during the healing process was monitored over 90 days.

2. Materials and Methods

2.1 Clinical Study design/Sample

This study was prospective, randomized, with a split-mouth controlled design. The study population was derived from patients under treatment at the School of Dentristy, Federal University of Pelotas/RS-Brazil between April 2015 and July 2016. The study report was drafted according to the CONSORT (Consolidated Standards of Reporting Trials) (Moher et al., 2010). The study was approved by the Ethics and Research Committee of the Institution (Protocol nº 1.458.507). All patients were informed regarding the nature of the study and their participation, and a written consent was granted by every participant, in accordance with the Helsinki Declaration of 1994.

The sample size calculation was based on two previous studies (Torroella-Saura, et al. 2015; Simunek et al., 2012) based on the Implant Stability Quotient (ISQ), considered the primary variable outcome for this study, using the following parameters: lower limit of the expected difference between means, standard deviation (SD) of the difference between means, a beta error of 10%, and a one-tailed alpha error of 5%. The minimal significant difference and SD for sample size estimation were calculated based on ISQ values. A minimum of twenty implants from each model for a study using paired samples are required to detect a mean difference of 6 points in ISQ with a standard deviation of 11 points, with alpha equal to .05 and a statistical power of 80%.

All patient enrolment, the same operators performed implant surgeries and follow-up evaluations. The patient’s inclusion criteria were: (1) 18 years of age or older (male or female); (2) Healthy medical conditions or without diseases that will compromise bone healing; (3) Missing 4 or more teeth in the posterior regions of the mandible with a desire to receive an implant-supported replacement; (4) Sufficient bone volume in the site to allow implant placement without the need for bone augmentation: at least a 5.0 mm diameter and 10.0 mm length as examined by Cone Bean Computed Tomography (CBCT).

A total of 12 exclusion criteria were applied: (1) unstable systemic disease (diabetes, hypertension, osteoporosis), medication or habit known to negatively influence bone healing and/or implant success (bruxism, clenching, heavy smokers); (2) active infection or inflammation in the areas intended for implant placement; (3) presence of uncontrolled or untreated periodontal disease; (4) history of smoking >10 cigarettes day (within past 12 months); (5) pregnant or lactating patients; (6) history of radiotherapy for head and neck; (7) history of bisphosphonates in the last 12 months; (8) current use of medications that adversely affect healing (corticosteroids, chemotherapeutic drugs); (9) immune-compromised condition; (10) systemic conditions that limit the surgical procedures; (11) grafting procedure necessity and (12) total edentulous patients.

2.1 .1 Preoperative Cone Bean Computed tomography

All patients underwent a CBCT scan prior to implant placement, for surgical planning and the assessment of the bone dimensions around the implant site. The linear measurements of bone beds were made with the DentalSlice programs (Bioparts, Prototipagem Biomédica, Brasília, DF, Brazil) or ImplantViewer (AnneSolutions, São Paulo, SP, Brazil). The tomographic slice used for measurement was selected based on the conventional spacing between implant and tooth (3.5mm) (Grunder, et al. 2005). The linear measurements were performed on a 4–mm slice (Figure 1-A) from the most anterior tooth for the mesial implant, and on a 8-mm slice for the distal implant (Figure 1-B). In these regions, the following bone measurements were done: total width and height of the jaw, widths of cortical tissue on the top, buccal and lingual side, and height and width of the medullary bone. The widths of the cortical and cancellous bone were measured in the region with the greatest extent. The proportion of cortical and cancellous bone was calculated for each bone site according to the methodology described by Simons et al. (2014). These linear measurements were used to further investigate the correlation between cortical and cancellous bone dimensions and the clinical variables IT, PS and SS.

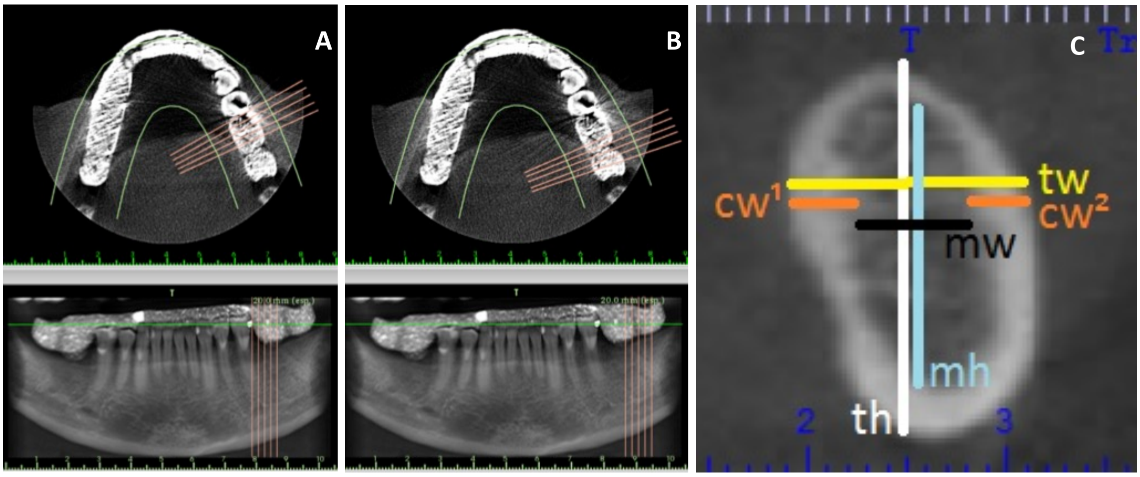


Figure 1. Location and measurements of the bony beds in a hemi-arch of the mandible from the last dental element of the arch **A.** Mesial Implant B. Distal Implant. **C.** CBCT slice measurements: total height (th) and width (tw); height (th - mh) and width (cw^1 + cw^2) of the cortical bone; and height (mh) and width (mw) of the medullary bone. The measurements were performed at the location with the greatest rim amplitude. Cortical boards of the buccal and lingual walls, as well as the alveolar crest were measured in loci adjacent to the previous measurements.

2.1.2 Implant designs and surgical procedures

A split-mouth design was planned, in which dental absences were randomly divided into four intervention groups, taking into account the need for each posterior hemiarch of the mandible to receive 1 cylindrical implant and 1 tapered implant. The implant design selection that was installed in each mandibular hemi-arch mandibular was performed by opaque envelope containing four numbers referring to macrogeometries. A pre-generated random sequence was created by one independent investigator (FF). The implant's type was randomized in the same manner as the implant placement sequence according to the implant design and position regarding the mesial and distal bone site. Opaque envelopes were sealed containing the sequence of implant design selection that was installed in each mandibular hemi-arch.

Each edentulous site of each patient was randomly assigned to one of the four implant macrogeometries. Immediately after flap elevation, an assistant indicated which implant had to be placed first following the indications contained in the sequentially numbered envelopes.

Four different macro designs were used in this study: the standard geometry Integra (IN) and three geometries that induce a 'healing chamber': Duo (D), Compact (C) and Infra (IF). The implant dimensions and drilling sequence are described below:

1) IN: cylindrical implant with a 4.00 mm diameter, 0.6 mm narrow pitch triangular threads and a 1.10mm flat cervical collar. Drilling sequence: 1) Twist drill 2.0mm; Twist step drills: 2.6mm; 3.0mm; 3.3mm 5) Coutersink drill 4.1mm.

2) D: tapered implant with a 4.60 mm diameter, 1.00mm stride trapezoidal thread in the body, a 1.90mm cervical necklace, and 0.45mm triangular narrow step microthreads. Drilling sequence: 1) Twist drill 2.0mm; 2) Twist step drills 2.6 mm,; 3) Tapered drill 4.6 mm; 4) Pilot drill 4.6mm.

3) C: cylindrical implant with 4.00mm diameter, 1.0 mm large pitch trapezoidal threads. Drilling sequence: 1) Twist drill 2.0 mm; 2) Twist step drills 2.6 mm, 3.0 mm, 3.3 mm, 3.8mm

4) IF: tapered implant with a 4.6 mm diameter, 1.5 mm large pitch trapezoidal threads. Drilling sequence: 1) Twist drill 2.0 mm; 2) Twist step drills 2.6 mm 3) Tapered drill 3.8 mm.

All implants had an identical length (10 mm) and surface (Vellox®, Signo Vinces, Campo Largo, PR, Brazil), which was treated with physicochemical subtraction by means of abrasive blasting and acid treatment. Figure 2 shows the implant installation sequence as well as the effect of the "healing chamber" created by each drilling protocol based on the dimensions of the bone bed.

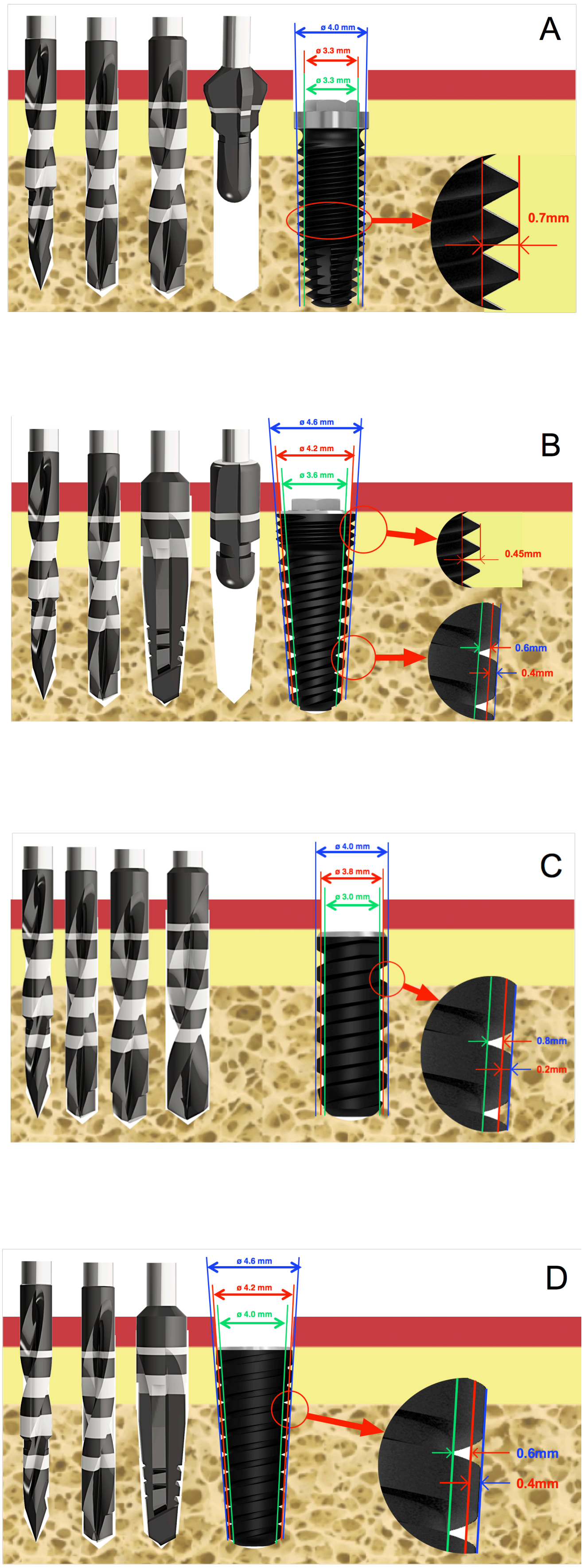

A
ø 4.0 mm
ø 3.3 mm
ø 3.3 mm
0.7mm
B
ø 4.6 mm
ø 4.2 mm
ø 3.6 mm
0.45mm
0.6mm
0.4mm
C
ø 4.0 mm
ø 3.8 mm
ø 3.0 mm
0.8mm
0.2mm
D
ø 4.6 mm
ø 4.2 mm
ø 4.0 mm
0.6mm
0.4mm

Figure 2. Implants drilling sequence: a.) Integra; b.) Duo; c.) Compact; d) Infra. Red line indicates the diameter of the bone bed resulting from bone drilling. Blue line indicates the diameter of the implant body; Green line indicates the inner diameter of the implant based on the thread valley.

After administering local anesthesia (Articaine 4% with epinephrine 1:100,000 - New DFL, RJ / Brazil), drilling was performed following the manufacturer's recommendation for each type of implant. The drill sites were irrigated with distilled water, and the surgeon also recorded the bone type during drilling. The insertion of the implants was performed by reducing the angle counter (30 rpm) without irrigation, and installation was completed with a surgical torque wrench (Signo Vinces, Campo Largo/PR - Brazil). All implants were installed at the bone crest level. The IT values, were determined as the maximum torque value (N/cm) reached at the end of the insertion of the implant in the recipient site.

Subsequently to final seating of the implant, a type 4 or type 38 Smartpeg® was screwed into each implant, and a resonance frequency analysis (RFA) was performed using an OsstellMentor® device (Ostell/Integration Diagnostics, Goteborg, Sweden) to record the primary stability (PS). The implant stability quotient values (ISQ) were recorded in the buccal and the mesial directions, both oriented perpendicular to the transducer. The implant stability was also recorded postoperatively at 7, 14, 21, 42, 60, and 90 days to determine the secondary stability (SS).

Straight healing abutments with a diameter of 4.1 mm and height of 2–4mm were inserted after the implant installation; they were removed and reinserted after each measurement in the subsequent follow-up periods. The incision was sutured with 5.0 nylon (Bioline Fios Cirúrgicos Ltda, GO, Brazil) using simple interrupted stitches, which were removed one week after surgery. All patients were instructed to follow a doughy and cold diet in the first three days after surgery, along with instructions for oral hygiene. Special care for the biofilm in the surgical site was prescribed to patients (soft tooth brush and mouth rinsing twice daily for 1 week with a solution of 0.2% of chlorhexidine digluconate) and this was reinforced at each follow-up. All patients received a prescription with Azithromycin 500mg, 1 tablet every 24 hours for 3 days, starting 1h before surgery. Additional prescriptions included dexamethasone 4 mg, 1 tablet every 24 hours for 3 days and Lisador or Paracetamol 500mg, 1 tablet 6/6 hours for 5 days. No implant-supported temporary crowns were used during the first 12 weeks after implant placement.

The biological osseointegration success was determined by evaluating peri-implant health. The main sign of tissue damage is an inflammatory process, which was reported during the healing period (Salvi & Lang, 2004). The 3 diagnostic criteria were:

(A) visible plaque index (VPI): 0 = no plaque; 1 = detected with sonar use; 2 = visible; 3 = abundant

(B) presence of calculus (CC): 0 = absent; 1 = present

(C) the degree of peri-implant inflammation (PI): 0 = normal mucosa; 1 = mild inflammation, little color change, and slight edema; 2 = moderate inflammation, redness, swelling, and shine; 3 = severe inflammation, marked redness, swelling, and soreness.

The data were collected 7, 14, 21, 42 and 90 days after surgery. To minimize bias, all implants were installed by the same surgeon, and all data collection was performed by a blinded single dentist.

2. 1.3 Success criteria

Successful implants were those that met the following criteria (Lang & Zitzmann, 2012): (1) absence of persistent pain or dysesthesia; (2) absence of peri-implant infection with suppuration; (3) absence of mobility; (4) no continuous peri-implant radiolucency; and (5) less than 1.5 mm of marginal bone resorption.

The primary outcome variables were insertion torque and implant stability changes. Secondary outcomes were peri-implant health monitoring (VPI, CC and PI), failures of the implants that required their removal, any surgical complications occurred during the entire follow-up.

2.2 Statistical analysis

Statistical analysis was performed using SAS (release 9.3, SAS Institute Inc). Data were assessed for normality using the asymmetry and kurtosis coefficients followed by the Shapiro-Wilk test. A one-way ANOVA was used to investigate differences in IT and linear bone dimensions between the macrogeometry groups. The repeated measurements ANOVA test or ANOVA-R was used for analysis of ISQ, VPI and PI. This was followed by the Tukey Kramer Test or Student's t test for comparisons between the groups or within each macrogeometry. The variables VPI, PI and presence of calculus were not dichotomized and were presented as means and standard deviations of the registered scores. Variables that were close to zero were not subjected to statistical analysis (e.g., presence of calculus). The Spearman correlation test was performed to investigate the associations between: i) bone and mechanical characteristics (IT x PS), ii) bone type and type of implant, iii) IT and ISQ in all periods of time. The level of significance was set at $\alpha=0.05$ for all tests.

4. Results

4.1 Study population: demographic, bone type and implant data

This study included 24 patients with an average age of 53.6±9.6 years: 13 women and 11 men; 4 patients were smokers. A total of 99 implants were installed in the posterior mandibular region: 5 in the first premolar region, 14 in the second premolar region, 46 in the first molar region and 34 in the molar second region (Figure 3). No implants were lost during the follow-up period.

The statistics related to the sample composition and the categorical variables (bone type, implant macrogeometry and IT) are summarized in Table 1. Bone type II accounts for 65.66% of the sample, while type I and type III account for 16.16% and 18.18%, respectively. The IT data is presented in two ways. Firstly, the raw data were evaluated. This revealed 10 registered torque values (20, 30, 32, 40, 45, 50, 55, 60, 65 and 80). There is strong evidence for differences between the proportions of these torque values in the sample ($p=0.0001$). These values were subsequently categorized in high torque and low torque groups, using an arbitrary torque of 45N/cm for subdivision. High torque was observed in 61 cases (62.89%), which was significantly higher ($p=0.0111$) than the remaining 36 cases with low torque (37.11%).

The characteristics of the operated bone sites are shown in Table 2, where they are grouped according to the implant macrogeometry. These data show that bone sites that received different dental implants presented statistically similar dimensions ($p<0.05$), with the exception of the buccal cortex width. The buccal cortex width was found to be significantly lower in bone sites with Integra (IN) dental implants ($p=0.02$, Tukey Kramer Test). There was strong evidence for differences in bone type proportions in the sample ($p <0.01$).

Table 1. Frequencies, percentages, and chi-square test (χ^2) for equality of proportions among the categorical variables.

Variables/Categories	Frequency	Percentage	χ2	Freedom Degree	p-value
Gender					
Female	55	55.56	1.22	1	0.2689
Male	44	44.44			
Bone type					
I	16	16.16	46.61	2	0.0001
II	65	65.66			
III	18	18.18			
Implant Macrogeometry					
Integra (IN)	26	26.26	0.11	3	0.9905
Duo (D)	24	24.24			
Compact (C)	24	24.24			
Infra(IF)	25	25.25			
Insertion Torque					
20	4	4.12	101.87	9	0.0001
30	2	2.06			
32	5	5.15			
40	1	1.03			
45	24	24.74			
50	10	10.31			
55	2	2.06			
60	19	19.59			
65	1	1.03			
80	29	29.90			
Grouped Insertion Torque					
Low (≤45 N/cm)	36	37.11	6.44	1	0.0111
High (>45 N/cm)	61	62.89			
Age (years)					
26 |—| 40	14	14.14	10.78	3	0.0130
40 —| 50	21	21.21			
50 —| 60	36	36.36			
60 —| 70	28	28.28			

Table 2. Description of the dimensional characteristics of bone site: mean and SD for the linear measurements (mm) in the cortical bone and in the medullary bone (One Way ANOVA, Tukey Kramer Test). Abbreviations: Total height (Th); Buccal cortex width (Bcw); Lingual cortex width (Lcw). Different capital letters represent groups with statistically significant differences.

	Cortical Bone			**Medular bone**			
Implant	**Th**	**Bcw**	**Lcw**	**Th**	**Width**	**% Height**	**% Width**
Integra	1.51 (1.23) A	3.19 (0.99) A	2.73 (0.75) A	19.86 (4,25) A	5.44 (1,19) A	75.62 (9.92) A	46.81 (7.10) A
Duo	1.83 (1.38) A	2.98 (0.61) AB	2.81 (0.70) A	18.92 (3,29) A	5.81 (1,71) A	76.29 (8.04) A	49.41 (11.01) A
Compact	2.10 (1.85) A	2.79 (0.58) AB	2.75 (0.61) A	19.12 (4,01) A	5.38 (1,57) A	76.40 (9.25) A	46.66 (8.85) A
Infra	1.42 (0.99) A	2.56 (0.74) B	2.93 (0.73) A	20.17 (3,06) A	5.46 (1,37) A	77.57 (5.73) A	48.53 (9.37) A

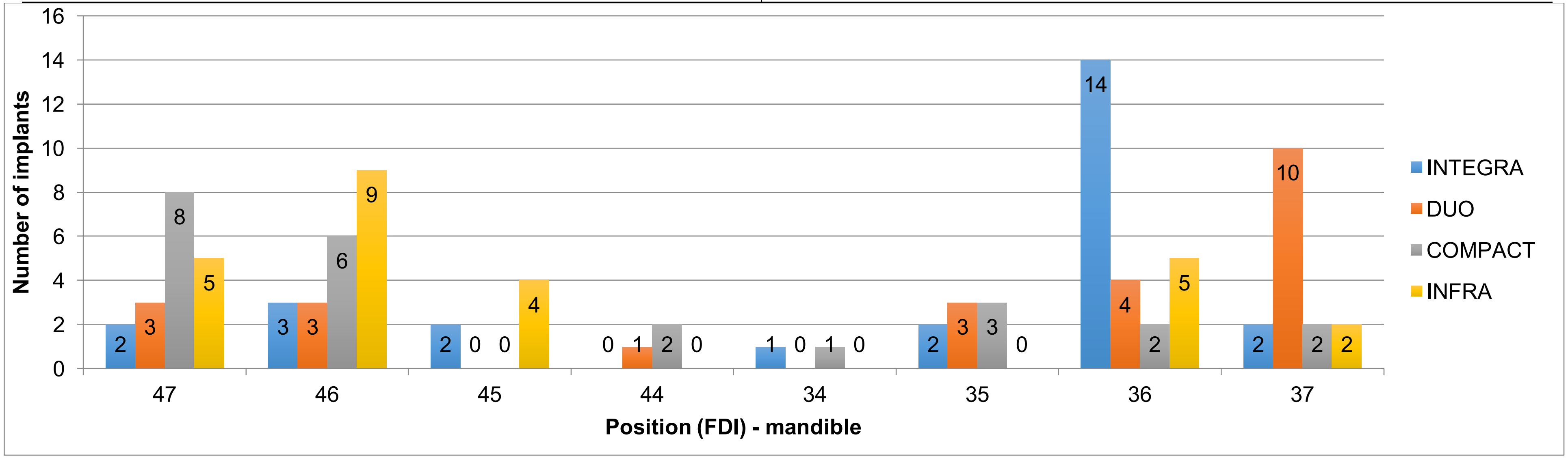


Figure 3. Distribution of the anatomical implant site

4.2. Insertion Torque

The IT values registered by the surgeon were not statistically different between the 4 implant macrogeometries (p = 0.8061). The IT values and the distribution of the bone type in the surgical sites according to the macrogeometry of the implants are shown in Table 3. The chi-square test (G^2) for independence of proportions did not find any significant association between bone type and implant geometry ($p>0.05$).

The IT showed significant differences between the different bone types (Table 4). The IT values recorded in bone type III were significantly lower than the mean values of bone types I and II (p=0.025). In addition, an association was found between bone type and the 2 IT categories. Finally, Pearson's correlation test showed a significant positive association between IT and total height of the bone site (r = 0.2504; p = 0.0149) and IT and thickness of the lingual cortical (r = 0.2621; p = 0.0107). Conversely, a significant negative association was found between insertion torque and medullary thickness (r = -0.2193, p = 0.0337). Dispersion diagrams are shown in the Supplementary material.

Table 3. Insertion Torque Mean (SD) according to the implant type and frequency (%) of dental implants installation according to bone type.

	Insertion Torque	**Bone Type**		
Implant		**Type I**	**Type 2**	**Type 3**
Integra	57.19 (21.03) A	18 (75%)	4 (16.6%)	4 (16.6%)
Duo	56.87 (15.38) A	3 (12.5%)	17 (70.8%)	4 (16.6%)
Compact	54.52 (21.19) A	4 (16.6%)	16 (66.6%)	4 (16.6%)
Infra	57.04 (16.26) A	5 (20.8%)	14 (54.1%)	6 (25%)

G^2= Statistics: 1.57; Degrees of Freedom: 6; p-value: 0.9549.

Table 4. Insertion Torque means (SD) and frequency (%) of dental implants according to insertion torque category (Low and High).

Bone type	General IT	Insertion Torque category*	
	Mean (SD)	Low (<= 45N)	High (> 45N)
I	65.94 (18.5) A	2 (12.50)	14 (87.50)
II	58.20 (16.15) A	24 (37.50)	40 (62.50)
III	45.59 (17.13) B	10 (58.82)	7 (41.18)

*G^2= Statistics: 8.18; Degrees of Freedom: 2; p-value: 0.0167.

4.3 Resonance frequency analysis (RFA)

Resonance frequency analysis provides strong evidence (ANOVA, p<0.01) for differences between at least two of the ISQ mean values. The absence of a significant interaction effect for the ISQ values shows that the magnitude of the time effects is similar for the four implant types. The 7 days ISQ values were significantly lower than those at all other time points, except the ISQ values at 14 days, as shown in Figure 4.

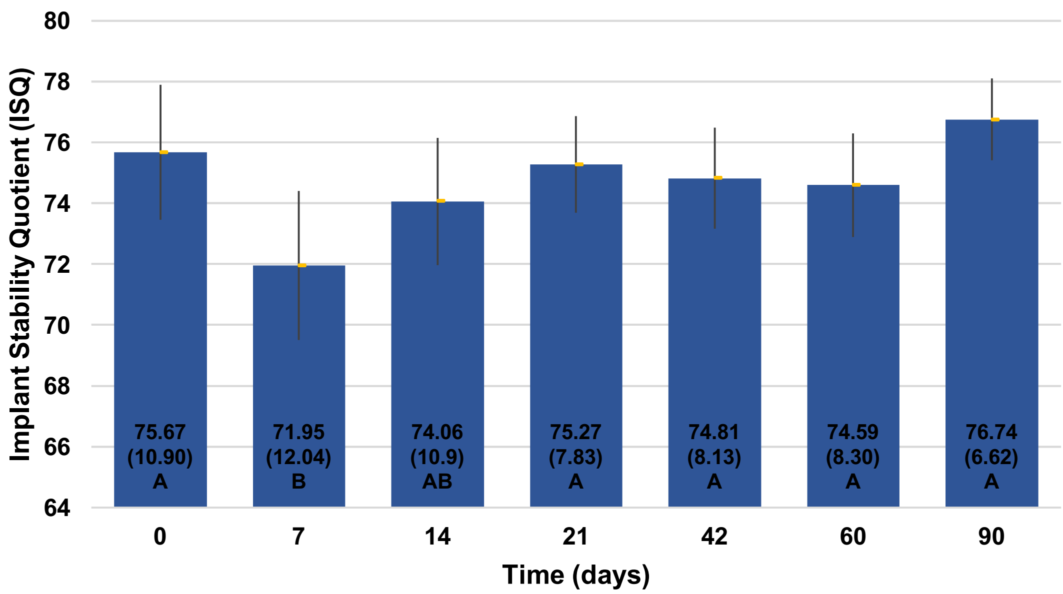


Figure 4. Mean (SD) and mean confidence limits (95%) for the implant stability quotient (ISQ) as a function of time. Capital letters indicate groups with statistically identical ISQ averages at a significance level of 5% (Tukey Kramer test).

Regarding the association study between bone characteristics and primary implant stability (baseline ISQ), Pearson's correlation test showed a significant negative association between ISQ value and total bone width ($r = -0.2865$; $p = 0.0054$) and, between ISQ value and buccal cortical width ($r = -0.22227$, $p = 0.0319$). The dispersion diagrams are shown in the supplementary material. Unlike the IT values, ISQ values were not significantly associated with the bone type when data were categorized based on a cut off value of 75, which corresponds to the median ISQ value for the sample population (G^2 statistic: 0.622; Degrees of Freedom: 2; p-value: 0.7325).

4.4 Peri-implant health analysis

Calculus was not detected in any of the evaluated implants. The results of a one-way ANOVA presented in Table S1 show significant interactions between implant type and time. The results show that the most critical time period for the VPI was 7 days, with significant differences between the implant macrogeometries. In addition, the Integra and Duo implants presented significantly higher VPI scores compared to the means of the other time intervals (Figure 5). Conversely, Compact and Infra implants did not show significant differences between the means over the monitored healing time.

The degree of peri-implant inflammation showed a significant interaction with the time interval ($p=0.0001$). A significant successive decrease can be observed from 7 to 21 days. After 21 days, the IP reached the stable scores which do not differ significantly from the IP scores at 42 and 90 days. Figure 6 illustrates the IP scores over the time for each implant macrogeometry.

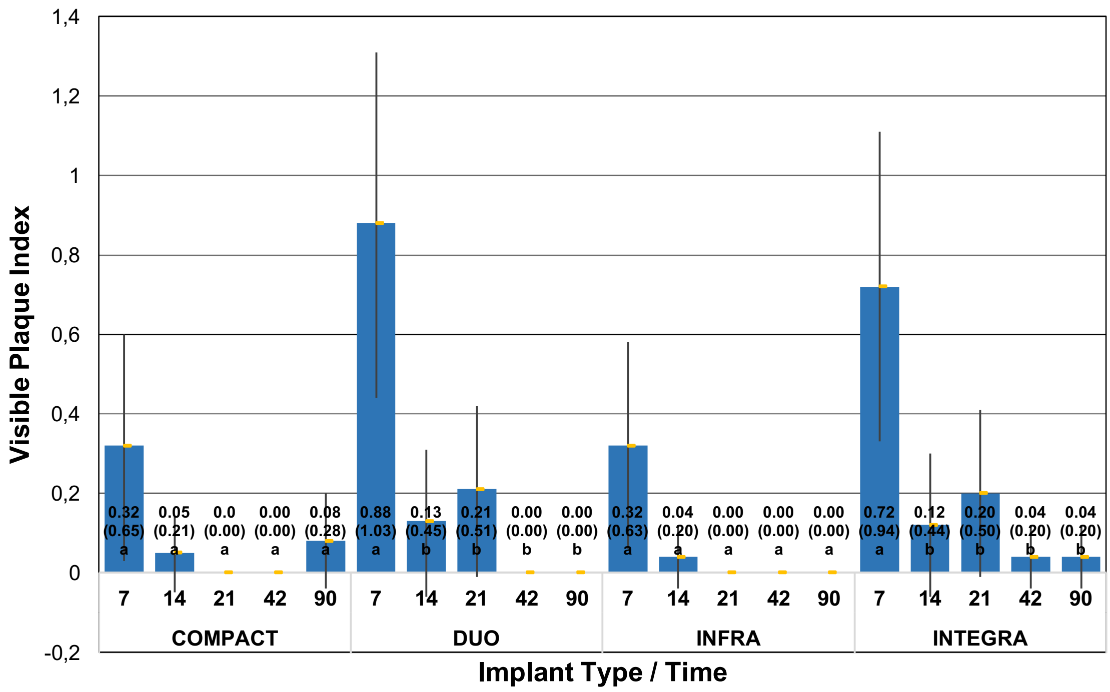


Figure 5. Mean (SD), confidence limits of the mean (95%) and Tukey-Kramer test. Different capital letters indicate groups with statistically identical VPI averages; P<0.05)

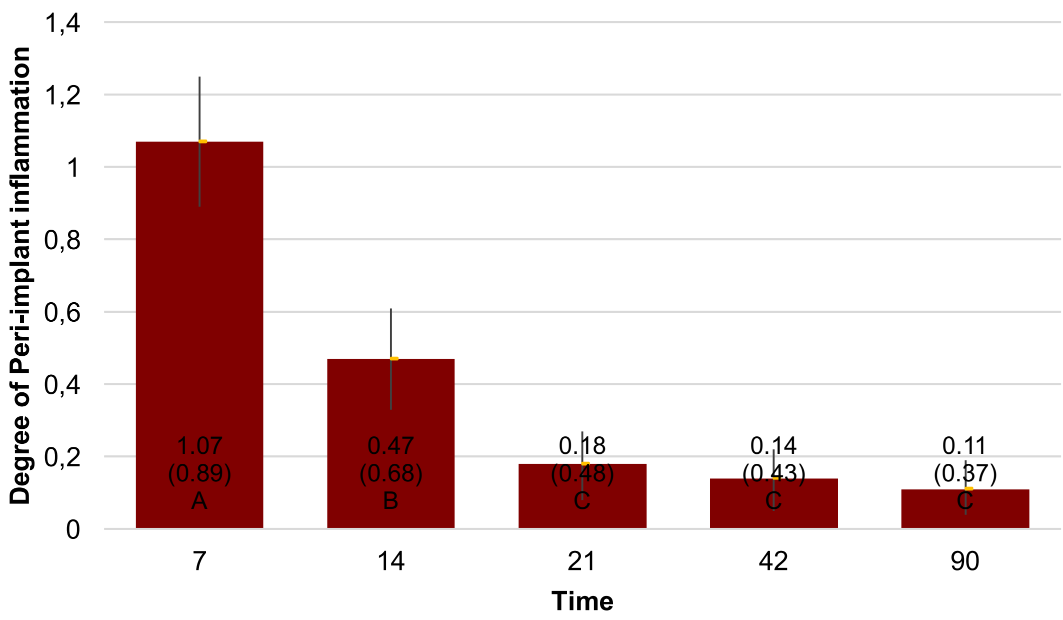


Figure 6. Mean (SD) and 95% confidence intervals according to the scores for peri-implant inflammation. Bars with similar letters show means with no significant differences for PI (p <0.05) over time.

4.5 Insertion Torque x Implant Stability

The interaction between the implant stability quotient (ISQ) and the insertion torque at different time periods is presented in Table 6. This data shows that there is no significant association between both primary stability predictors for all implant macrogeometries. Integra and Compact implants show a significant association between IT and ISQ values at 42 days ($p < 0.05$). The positive correlation coefficients can be considered as moderately strong (Integra r: 46.76% and Compact r: 43.06%). The Duo implants ($p < 0.05$) show an association between ISQ and IIT values at 60 days and at 90 days periods. The latter period presents the most significant association ($p < 0.01$), with a high correlation coefficient of approximately 60%. The Infra implants record a significant association between ISQ and IT ($p < 0.05$) at 14 days with a moderately positive correlation coefficient (r: 41.99%).

Table 6. Pearson Correlation Coefficients (r) and test for independent hypothesis between Insertion Torque and implant stability (ISQ) for each time interval according to the implant macrogeometry. Results described as a function of the proximity of the p-value with the level of significance.

Time	Implant Macrogeometry			
	Integra	Duo	Compat	Infra
0	-0.1274 (0.5623)	0.1277 (0.5522)	0.20859 (0.3516)	0.2775 (0.1793)
7	0.1121 (0.6106)	0.2172 (0.3079)	0.24439 (0.2730)	0.3021 (0.2028)
14	0.2321 (0.2866)	0.1920 (0.3688)	0.27243 (0.2200)	**0.4199 (0.0367)**
21	-0.0455 (0.8366)	0.0791 (0.7132)	0.24094 (0.2801)	0.3452 (0.0910)
42	**0.4676 (0.0245)**	0.3631 (0.0886)	**0.43062 (0.0513)**	0.2885 (0.1619)
60	0.0267 (0.9039)	**0.5028 (0.0145)**	0.32177 (0.1549)	0.0601 (0.7754)
90	-0.1251 (0.5602)	**0.5964 (0.0027)**	-0.07412 (0.7431)	0.0462 (0.8265)

4.6 Complications and failures

After three months, periapical radiographs were performed to evaluate the health and integrity of the peri-implantar bone tissue, prior to prostheses confection. At the end of this period, 3 implants failed being 2 Integra and 1 Compact. Some complications restricted to the surgical bed were detected during the study. Two bone sites showed symptoms and inflammation of the peri-implant tissue, while mild inflammation and mobility was observed in the 3 dental implants that failed. At the end of the study, success rates were 100% for the Duo and Infra implants, 95.8% for Compact and 92.3% for Integra. The lost implants were removed and replaced.

5. Discussion

This randomized, split-mouth clinical study compared the biological performance of four implant macrogeometries: one conventional and three geometries inducing a “healing chamber”, a relatively novel concept (Leonard et al., 2009; Coelho et al., 2010; Coelho et al., 2011; Jimbo et al., 2014; Coelho et al., 2015a; Coelho et al., 2015b). According to the drilling protocols, the installation of these implants which create a healing chamber and while exerting a minimum compression to the bone could compromise the primary and secondary stability of implants during the early healing process.

During sample selection and randomization, great care was taken to avoid a number of confounding factors that could influence the implants’ performance. Table 2 shows that the bone sites for the 4 implant macrogeometries had similar dimensional characteristics for both the cortical bone and medullary bone, except for small differences in buccal cortex dimensions. This study design minimizes differences in bone availability as a confounding factor. This is especially important in our study, because it is expected that the drilling protocol is the main factor responsible for the creation of a healing chamber. In addition, the drilling protocol proposed by the manufacturer is also determined by the implant macrogeometry, since it is well established that the relationship between the shape of the threads and their shear strength during the implant placement will modulate the bone compression or expansion (Figure 2).

Surprisingly, our clinical findings showed no significant differences between the primary stabilities of the 4 studied implants (Table 2). The mean IT values of 54.52 ± 21.19 N/cm and 57.19 ± 21.03 N/cm can be considered high, and enable immediate loading. The latter holds true even if single crowns were to be installed, which have a required insertion torque of 45N/cm for installation in the posterior mandible (Galucci et al., 2014). It is interesting to note that, when the implants were classified in low (≤45

N/cm) and high torque categories (>45N/cm), the influence of bone characteristics in this outcome was found to be significant (Table 4). Furthermore, the proportion of high insertion torque values was significantly higher implants in bone type I and II than for implants in bone type III, irrespective of the implant macrogeometry. The high proportion of implants installed with high insertion torque (61%) poses a risk, because recent clinical findings from Barone et al. (2016) indicated that torques greater than 50N/cm may induce pronounced peri-implant bone remodeling and buccal soft tissue recession (Barone et al., 2016).

A significant positive correlation was detected between insertion torque and total height of the bone site and thickness of the lingual cortical bone. In this microenvironment, it also seems that the medullary thickness negatively contributes to the insertion torque values. The insertion torque is also influenced by the microscopic and macroscopic characteristics of the bone bed together with the surgical technique and ability (Menicucci et al., 2012). The design and type of implant surface may also improve primary stability (Nedir et al., 2004; Lioubavina-Hack et al., 2006). However, our study adopted four types of implants with the same type of surface treatment, and differ mainly in implant shape, which is either cylindrical or conical. Another important factor that could have limited the detection of differences using IT is that the primary stability was measured manually with a surgical wrench.

The primary stability was also measured by resonance frequency analysis. The mean ISQ values were not statistically different between the studied implant groups, showing that the stiffness of the implant bone interface during surgery was independent of the implant macrogeometry. Our study found high ISQ values for primary and secondary stability, with ISQ values between 71.95±12.04 and 76.74±6.62. Higher primary stability reduces the risk of micromotion and adverse tissue response by reducing the implant failure risk (Javed et al., 2013). The high ISQ values obtained refer to the IT values for immediate loading (Sennerby & Meredith, 1998). Our study could have adopted the immediate loading protocol for the 3new implant macrogeometries that form a healing chamber. However, because this is the first study reporting ISQ values for these geometries, it could not be predicted that these high ISQ values would be maintained over time. Furthermore, it is important to note that increased ISQ values can be reached after osseointegration with conventional loading procedures, and this concept has increased the predictability of success rates and also decreases the risk of long-term failure (Baltayan et al., 2016). This is especially important when the clinical performance of new implant designs is tested.

Significant correlations between ISQ values that serve as a proxy for primary stability, and bone characteristics were also found. Unlike the IT values, the ISQ values were negatively correlated with the total bone width and buccal cortical width. In addition, when the median of the ISQ values in this study (75) was established as a cut off value, no association between ISQ and bone type was found, even though the former is related to the bone stiffness. The median ISQ values of 75 immediately after the implant installation can be considered high for these 4 implant systems. Although certain universal ISQ cut off values for immediate or conventional loading in different regions of maxilla and mandible are available in literature (Baltayan et al., 2016; Shiffler et al., 2016), some studies have shown that comparisons between ISQ values for different implant systems should be made with caution (Lozano-Carrascal et al., 2016; Rabel et al., 2007). In this sense, our study provides information about a specific manufacturer, and describes ISQ values that can be used to make an early identification of implants stability from early stages of healing until osseointegration is complete.

The secondary stability showed statistical differences at some time intervals. The average ISQ values decreased significantly after 7 days. These values subsequently increased rapidly between 7 and 14 days, achieving ISQ values that are intermediate between the values at 0 and 7 days and statistically identical to the ISQ values at 0, 7 and 21 days. After 21 days, the ISQ values remained stable until the end of the follow up time (90 days). This biological response can be considered early compared to previous studies, which reported a transition between the primary and secondary stability after 21 days of healing (Park et al., 2010). The significant reduction of around 10% in the ISQ values during the first week did not interfere in bone-implant surface stiffness, affecting the bone healing and remodeling. However, it is known that the stiffness of bone itself, and bone density as well as the ratio of cortical and cancellous bone also affects RFA.

The stiffness of implant components can influence the ISQ values and is affected by the interlocking structures, and the composing elements of the materials (Atsumi et al., 2007; Sennerby and Meredith, 2000). Bone and implant surface stiffness may be affected by using a small-diameter final drill, changes in surgical techniques such as bone compaction technique, self-tapping design implants and wide tapered implants, but not by implant length. This clinical study also assessed whether the implant stability reached during the installation could be maintained during the healing period. Macroscopic differences of the implant and bone drilling recommended for the creation of the healing chamber can result on different micromotion levels. Monitoring micromotion with resonance frequency analysis enables detection of a temporary ISQ drop that identifies the onset and duration of bone remodeling. Many aspects of implant macrogeometry can influence bone remodeling, such as the implant body design (Torroella-Saura, 2016; Rabel et al., 2007), the thread pattern (pitch, depth, shape) (McCullough & Klokkevold et al 2016;) and the cervical collar design (Pozzi et al., 2014).

Our results identified distinct biological behaviors in the intragroup comparisons until the secondary stability was reached. The Integra, Duo and Infra models showed a significant drop in ISQ values already in the first week of healing. Conversely, the ISQ values of the Compact implant were significantly lower only after the second week of healing, and maintained this stability until the end of osseointegration. The stable osseointegration for the Compact implant can be attributed to a larger healing chamber created by the cylindrical shape in combination with the drilling protocol. The latter contrasts sharply with the behavior of the Infra implant, which did not maintain the value reached at the time of installation and showed 2 significant drops in the ISQ values. Although these ISQ values are still biologically acceptable and small significant changes were observed in the secondary stability, this behavior is probably related to the high insertion torques achieved for all implants and the controlled bone availability of the patients in the study.

Our study did not find an association between insertion torque and primary stability (ISQ). However, the relation between insertion torque and secondary stability measured by ISQ showed correlations for some macrogeometries at several time intervals. The Infra implants showed a significant association between ISQ and IT at 14 days with a moderately positive correlation coefficient (r: 41.99%). In addition, Integra and Compact implants presented a statistically significant, moderately strong association between IT and ISQ values at 42 days (r: Integra r: 46.76% and Compact r: 43.06%). Finally, the Duo implants showed a strong association between ISQ and IT values at 60 days (r: 50.28%) and at 90 days (59.64%) periods. These results indicate that both cylindrical implants presented similar behavior during bone healing, achieving a bone stiffness comparable to those registered during the implant surgery. The relationship between these properties seems to be different for the conical implants, since Infra reached significant association in the early stages of healing, while Duo reaches this condition in the last stages. The latter could be related to the microthreads present in the Duo macrogeometry, which require an active role of the cortical bone to stimulate healing and promote a bone implant site with the similar mechanical properties.

The implant design is thought to influence the biomechanical behavior of the implants, especially the presence of microthreads in the implant collar and the implant body shape extensively studied in animal studies (Kwon et al.,2013; Chowdhary et al., 2014), *in vitro* (Ameida et al., 2013; Ferraz et al., 2012) and *in silico* studies (Amid et al., 2013; Choi et al., 2012; Hudieb et al., 2011). This is in agreement with the behavior of the Duo implants that presented the highest ISQ values after 2 weeks of healing (77.85±8.82). The shape of the implant body determines the homogeneity of the tension distribution (Valente et al., 2015). At this moment, the differences in mechanical and biological behavior of cylindrical and tapered implants are still debated. Our study did not observe systematic differences in ISQ between the cylindrical (Integra, Compact) and the tapered (Duo, Infra) implants used. Direct comparison between both geometries is not always possible, because some tapered implants have a modified cervical region incorporating microthreads to increase the primary stability (Wilson et al., 2016) and longitudinal data related to the peri-implant behavior are still missing.

Clinically, minor changes in peri-implant health were observed for all implants during the healing period. The changes observed in the VPI and IP indexes were limited to temporary, minor increases for some implants during the first week of healing. The healthy peri-implant tissue of all patients can be attributed to the good overall health of the sample. This was further aided by the permanent hygiene enhancement by the healing caps and their removal and cleaning at each follow-up session. The connection and disconnection of the healing caps during the implant stability monitoring did not cause any damage to the implants. Therefore, the implant failures in this study cannot be related to the implant mobility observed during the ISQ measurements. The latter mobility was previously attributed as a causal factor for implant failures, but this was contradicted by the results from Koutouzis et al. (2013).

Finally, some limitations for this clinical study must be pointed out. The insertion torque peaks could not be registered precisely, because this requires additional data including the insertion time over implant length ratio. The implants did not undergo prosthetic loading and the influence of masticatory loads on the evolution of secondary stability is not determined. Furthermore, the implants were installed in non-critical bone areas without limiting bone density, bone availability or bone impairment conditions. There is currently a limited amount of studies available comparing osseointegration rates of different implants surfaces and macrogeometries. The latter is also the case for studies comparing the inflammatory response during the healing process and quantifying the potential oesteoinumological biomarkers that can be involved in the osseointegration.

6. Conclusion

The four-studied implant macrogeometries did not affect the primary stability nor the peri-implant health during the 90 days healing period. However, the implant macrogeometries affected the initial of secondary stability with large differences at 7 and 14 days irrespective of implant type.

References

1. Almeida EO, Freitas Júnior AC, Bonfante EA, Rocha EP, Silva NR, Coelho PG. Effect of microthread presence and restoration design (screw versus cemented) in dental implant reliability and failure modes. Clin Oral Implants Res. 2013 Feb;24(2):191-6.
2. Alsaadi G, Quirynen M, Michiels K, Jacobs R, van Steenberghe D. A biomechanical assessment of the relation between the oral implant stability at insertion and subjective bone quality assessment. J Clin Periodontol. 2007 Apr;34(4):359-66.
3. Amid R, Raoofi S, Kadkhodazadeh M, Movahhedi MR, Khademi M. Effect of microthread design of dental implants on stress and strain patterns: a three-dimensional finite element analysis. Biomed Tech (Berl). 2013 Oct;58(5):457-67.
4. Atsumi M, Park SH, Wang HL. Methods used to assess implant stability: Current status. Int J Oral Maxillofac Implants. 2007;22:743–54.
5. Baltayan S, Pi-Anfruns J, Aghaloo T, Moy PK. The Predictive Value of Resonance Frequency Analysis Measurements in the Surgical Placement and Loading of Endosseous Implants. J Oral Maxillofac Surg. 2016 Jun;74(6):1145-52
6. Barewal RM, Stanford C, Weesner TC. A randomized controlled clinical trial comparing the effects of three loading protocols on dental implant stability. Int J Oral Maxillofac Implants. 2012 Jul-Aug;27(4):945-56.
7. Barone A, Alfonsi F, Derchi G, Tonelli P, Toti P, Marchionni S, Covani U. The Effect of Insertion Torque on the Clinical Outcome of Single Implants: A Randomized Clinical Trial. Clin Implant Dent Relat Res. 2016 Jun;18(3):588-600.
8. Benic GI, Mir-Mari J, Hämmerle CH. Loading protocols for single-implant crowns: a systematic review and meta-analysis. Int J Oral Maxillofac Implants. 2014;29 Suppl:222-38.
9. Berglundh T, Abrahamsson I, Lang NP, Lindhe J. De novo alveolar bone formation adjacent to endosseous implants: A model study in the dog. Clin Oral Implants Res 2003;14(3):251–62.
10. Branemark PI, Adell R, Breine U, Hansson BO, Lindstrom J, Ohlsson A. Intra-osseous anchorage of dental prostheses. I. Experimental studies. Scand J Plast Reconstr Surg SWEDEN; 1969;3(2):81–100.
11. Chang PC, Lang NP, Giannobile WV. Evaluation of functional dynamics during osseointegration and regeneration associated with oral implants. Clin Oral Implants Res. 2010 Jan;21(1):1-12.
12. Choi KS, Park SH, Lee JH, Jeon YC, Yun MJ, Jeong CM. Stress distribution on scalloped implants with different microthread and connection configurations using three-dimensional finite element analysis. Int J Oral Maxillofac Implants. 2012 May-Jun;27(3):e29-38.
13. Chowdhary R, Halldin A, Jimbo R, Wennerberg A. Influence of Micro Threads Alteration on Osseointegration and Primary Stability of Implants: An FEA and In Vivo Analysis in Rabbits. Clin Implant Dent Relat Res 2013;562–9.
14. Chowdhary R, Jimbo R, Thomsen CS, Carlsson L, Wennerberg A. The osseointegration stimulatory effect of macrogeometry-modified implants: a study in the rabbit. Clin Oral Implants Res. 2014 Sep;25(9):1051-5.
15. Coelho PG, Jimbo R, Tovar N, Bonfante EA. Osseointegration: hierarchical designing encompassing the macrometer, micrometer, and nanometer length scales. Dent Mater 2015 Jan;31(1):37–52.
16. Coelho PG, Jimbo R. Osseointegration of metallic devices: current trends based on implant hardware design. Arch Biochem Biophys. 2014 Nov; 561:99–108.
17. Coelho PG, Suzuki M, Guimaraes MVM, Marin C, Granato R, Gil JN, et al. Early bone healing around different implant bulk designs and surgical techniques: A study in dogs. Clin Implant Dent Relat Res 2010 Sep;12(3):202–8.

18. Coelho PG, Suzuki M, Marin C, Granato R, Gil LF, Tovar N, et al. Osseointegration of Plateau Root Form Implants: Unique Healing Pathway Leading to Haversian-Like Long-Term Morphology. Adv Exp Med Biol 2015;881:111–28.
19. Doornewaard R, Christiaens V, De Bruyn H, Jacobsson M, Cosyn J, Vervaeke S, Jacquet W. Long-Term Effect of Surface Roughness and Patients' Factors on Crestal Bone Loss at Dental Implants. A Systematic Review and Meta-Analysis. Clin Implant Dent Relat Res. 2016 Nov 15. doi: 10.1111/cid.12457.
20. Dos Santos MV, Elias CN, Cavalcanti Lima JH. The effects of superficial roughness and design on the primary stability of dental implants. Clin Implant Dent Relat Res. 2011 Sep;13(3):215-23.
21. Ferraz CC, Anchieta RB, de Almeida EO, Freitas AC Jr, Ferraz FC, Machado LS, Rocha EP. Influence of microthreads and platform switching on stress distribution in bone using angled abutments. J Prosthodont Res. 2012 Oct;56(4):256-63.
22. Freitas AC, Bonfante EA, Giro G, Janal MN, Coelho PG. The effect of implant design on insertion torque and immediate micromotion. Clin Oral Implants Res 2012;23(1):113–8.
23. Gallucci GO, Benic GI, Eckert SE, Papaspyridakos P, Schimmel M, Schrott A, Weber HP. Consensus statements and clinical recommendations for implant loading protocols. Int J Oral Maxillofac Implants. 2014;29 Suppl:287-90.
24. Gehrke SA, da Silva UT, Del Fabbro M. Does Implant Design Affect Implant Primary Stability? A Resonance Frequency Analysis-Based Randomized Split-Mouth Clinical Trial. J Oral Implantol. 2015 Dec;41(6):e281-6.
25. Gottlow J, Barkamo S, Sennerby L. An Experimental Comparison of Two Different Clinically Used Implant Designs and Surfaces. Clin Implant Dent Relat Res
26. Huang HL, Chang YY, Lin DJ, Li YF, Chen KT, Hsu JT. Initial stability and bone strain evaluation of the immediately loaded dental implant: An in vitro model study. Clin Oral Implants Res 2011;22(7):691–8.
27. Hudieb MI, Wakabayashi N, Kasugai S. Magnitude and direction of mechanical stress at the osseointegrated interface of the microthread implant. J Periodontol. 2011 Jul;82(7):1061-70.
28. Huwiler MA, Pjetursson BE, Bosshardt DD, Salvi GE, Lang NP. Resonance frequency analysis in relation to jawbone characteristics and during early healing of implant installation. Clin Oral Implants Res. 2007 Jun;18(3):275-80.
29. Isidor F. Influence of Forces on Bone Osseo. Clin Oral Implants Res 2006;17(Suppl.2):8–18.
30. Ito Y, Sato D, Yoneda S, Ito D, Kondo H, Kasugai S. Relevance of resonance frequency analysis to evaluate dental implant stability: simulation and histomorphometrical animal experiments. Clin Oral Implants Res. 2008 Jan;19(1):9
31. Javed F, Ahmed HB, Crespi R, Romanos GE. Role of primary stability for successful osseointegration of dental implants: Factors of influence and evaluation. Interv Med Appl Sci. 2013 Dec;5(4):162-7.
32. Jimbo R, Janal MN, Marin C, Giro G, Tovar N, Coelho PG. The effect of implant diameter on osseointegration utilizing simplified drilling protocols. Clin Oral Implants Res 2014;25(11):1295–300.
33. Jimbo R, Tovar N, Anchieta RB, Machado LS, Marin C, Teixeira HS, et al. The combined effects of undersized drilling and implant macrogeometry on bone healing around dental implants: an experimental study. Int J Oral Maxillofac Surg 2014 Oct;43(10):1269–75.
34. Koutouzis T, Koutouzis G, Gadalla H, Neiva R. The effect of healing abutment reconnection and disconnection on soft and hard peri-implant tissues: a short-term randomized controlled clinical trial. Int J Oral Maxillofac Implants. 2013 May-Jun;28(3):807-14.
35. Kwon YS, Namgoong H, Kim JH, Cho IH, Kim MD, Eom TG, Koo KT. Effect of microthreads on removal torque and bone-to-implant contact: an experimental study in miniature pigs. J Periodontal Implant Sci. 2013 Feb;43(1):41-6.

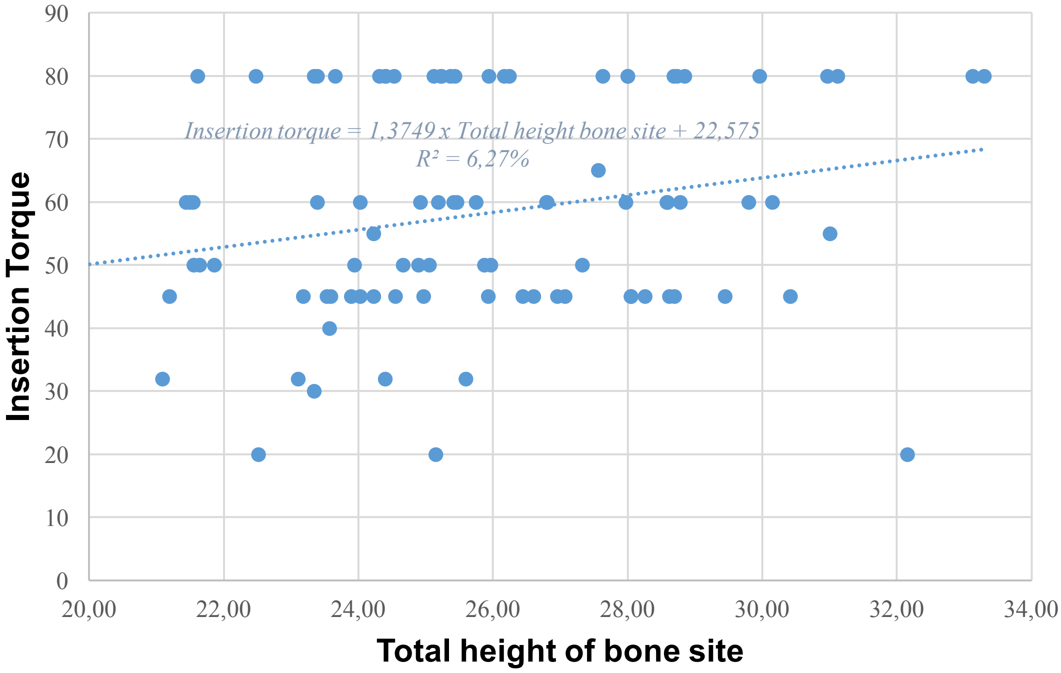
36. Lang NP, Salvi GE, Huynh-Ba G, Ivanovski S, Donos N, Bosshardt DD. Early osseointegration to hydrophilic and hydrophobic implant surfaces in humans. Clin Oral Implants Res 2011;22(4):349–56.
37. Lang NP, Zitzmann NU; Working Group 3 of the VIII European Workshop on Periodontology. Clinical research in implant dentistry: evaluation of implant-supported restorations, aesthetic and patient-reported outcomes. J Clin Periodontol. 2012 Feb;39 Suppl 12:133-8.
38. Le Guéhennec L, Soueidan A, Layrolle P, Amouriq Y. Surface treatments of titanium dental implants for rapid osseointegration. Dent Mater. 2007 Jul;23(7):844-54.
39. Leonard G, Coelho P, Polyzois I, Stassen L, Claffey N. A study of the bone healing kinetics of plateau versus screw root design titanium dental implants. Clin Oral Implants Res. Denmark; 2009 Mar;20(3):232–9.
40. Li H, Liang Y, Zheng Q. Meta-Analysis of Correlations Between Marginal Bone Resorption and High Insertion Torque of Dental Implants. Int J Oral Maxillofac Implants 2015;30(4):767–72.
41. Lioubavina-Hack N, Lang NP, Karring T. Significance of primary stability for osseointegration of dental implants. Clin Oral Implants Res. 2006 Jun;17(3):244-50.
42. Lozano-Carrascal N, Salomó-Coll O, Gilabert-Cerdà M, Farré-Pagés N,Gargallo-Albiol J, Hernández-Alfaro F. Effect of implant macro-design on primary stability: A prospective clinical study. Med Oral Patol Oral Cir Bucal. 2016 Mar 1;21(2):e214-21.
43. Marin C, Granato R, Suzuki M, Gil JN, Janal MN, Coelho PG. Histomorphologic and histomorphometric evaluation of various endosseous implant healing chamber configurations at early implantation times: a study in dogs. Clin Oral Implants Res 2010 Jun;21(6):577–83.
44. McCullough JJ, Klokkevold PR. The effect of implant macro-thread design on implant stability in the early post-operative period: a randomized, controlled pilot study. Clin Oral Implants Res. 2016 Oct 3.
45. Menicucci G, Pachie E, Lorenzetti M, Migliaretti G, Carossa S. Comparison of primary stability of straight-walled and tapered implants using an insertion torque device. Int J Prosthodont. 2012 Sep-Oct;25(5):465-71.
46. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ et al. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. BMJ. 2010;340:c869.
47. Nedir R, Bischof M, Szmukler-Moncler S, Bernard JP, Samson J. Predicting osseointegration by means of implant primary stability. Clin Oral Implants Res. 2004 Oct;15(5):520-8.
48. Norton M. Primary stability versus viable constraint--a need to redefine. Int J Oral Maxillofac Implants 2013;28(1):19–21.
49. Park JC, Kim HD, Kim SM, Kim MJ, Lee JH. A comparison of implant stability quotients measured using magnetic resonance frequency analysis from two directions: a prospective clinical study during the initial healing period. Clin Oral Implants Res. 2010 Jun;21(6):591-7.
50. Petrie CS, Williams JL. Comparative evaluation of implant designs: Influence of diameter, length, and taper on strains in the alveolar crest - A three-dimensional finite-element analysis. Clin Oral Implants Res 2005;16(4):486–94.
51. Pozzi A, Agliardi E, Tallarico M, Barlattani A. Clinical and radiological outcomes of two implants with different prosthetic interfaces and neck configurations: randomized, controlled, split-mouth clinical trial. Clin Implant Dent Relat Res. 2014 Feb;16(1):96-106.
52. Rabel A, Köhler SG, Schmidt-Westhausen AM. Clinical study on the primary stability of two dental implant systems with resonance frequency analysis. Clin Oral Investig. 2007 Sep;11(3):257-65.

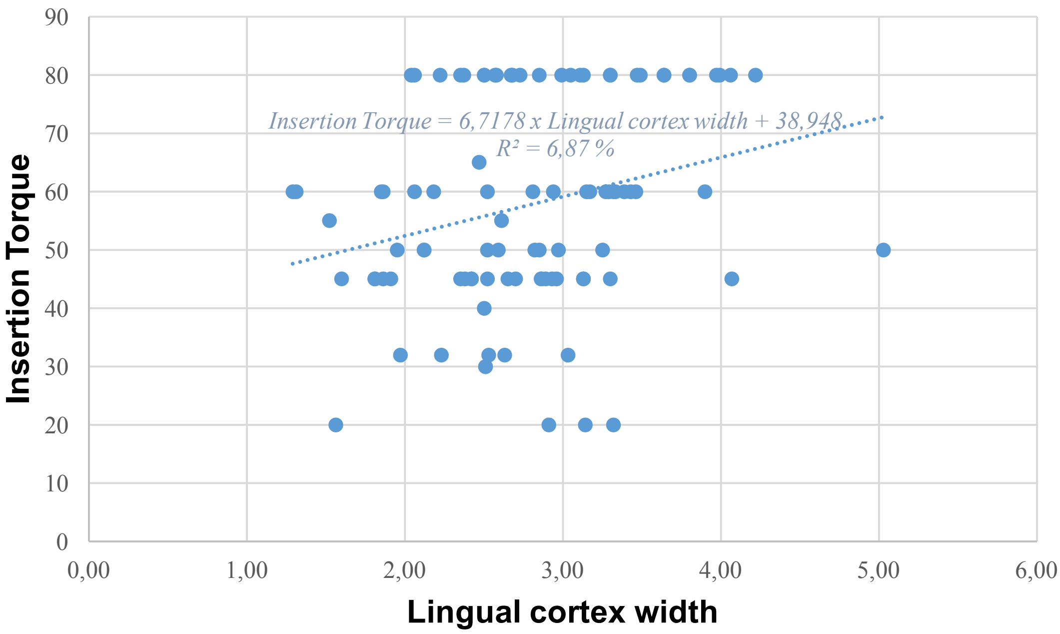
53. Raghavendra S, Wood MC, Taylor TD, Raghavendra S Taylor TD, WMC, Raghavendra S, Wood MC, et al. Early wound healing around endosseous implants: a review of the literature. Int J Oral Maxillofac Implants 2005;20(3):425–31.
54. Salvi GE, Lang NP. Diagnostic Parameters for Monitoring Peri-implant Conditions. Int J Oral Maxillofac Implants 2004;19(Suppl):116–27.
55. Santamaría-Arrieta G, Brizuela-Velasco A, Fernández-González FJ, Chávarri-Prado D, Chento-Valiente Y, Solaberrieta E, Diéguez-Pereira M, Vega JA, Yurrebaso-Asúa J. Biomechanical evaluation of oversized drilling technique on primary implant stability measured by insertion torque and resonance frequency analysis. J Clin Exp Dent. 2016 Jul 1;8(3):e307-11.
56. Schroeder A, Pohler O, Sutter F. [Tissue reaction to an implant of a titanium hollow cylinder with a titanium surface spray layer]. SSO Schweiz Monatsschr Zahnheilkd SWITZERLAND; 1976 Jul;86(7):713–27.
57. Sennerby L, Meredith N. Implant stability measurements using resonance frequency analysis: Biological and biomechanical aspects and clinical implications. J Periodontol. 2000;47:51–66.
58. Shiffler K, Lee D, Rowan M, Aghaloo T, Pi-Anfruns J, Moy PK. Effect of length, diameter, intraoral location on implant stability. Oral Surg Oral Med Oral Pathol Oral Radiol. 2016 Dec;122(6):e193-e198.
59. Simons WF, De Smit M, Duyck J, Coucke W, Quirynen M. The proportion of cancellous bone as predictive factor for early marginal bone loss around implants in the posterior part of the mandible. Clin Oral Implants Res 2015;26(9):1051–9.
60. Simunek A, Kopecka D, Brazda T, Strnad I, Capek L, Slezak R. Development of implant stability during early healing of immediately loaded implants. Int J Oral Maxillofac Implants. 2012 May-Jun;27(3):619-27.
61. Smeets R, Stadlinger B, Schwarz F, Beck-Broichsitter B, Jung O, Precht C, Kloss F, Gröbe A, Heiland M, Ebker T. Impact of Dental Implant Surface Modifications on Osseointegration. Biomed Res Int. 2016;2016:6285620.
62. Torcato LB, Pellizzer EP, Verri FR, Falcón-Antenucci RM, Santiago Júnior JF, de Faria Almeida DA. Influence of parafunctional loading and prosthetic connection on stress distribution: a 3D finite element analysis. J Prosthet Dent. 2015 Nov;114(5):644-51
63. Torroella-Saura G, Mareque-Bueno J, Cabratosa-Termes J, Hernández-Alfaro F, Ferrés-Padró E, Calvo-Guirado JL. Effect of implant design in immediate loading. A randomized, controlled, split-mouth, prospective clinical trial. Clin Oral Implants Res. 2015 Mar;26(3):240-4.
64. Valente ML, de Castro DT, Shimano AC, Lepri CP, dos Reis AC. Analysis of the influence of implant shape on primary stability using the correlation of multiple methods. Clin Oral Investig. 2015 Nov;19(8):1861-6.
65. Wang T-M, Lee M-S, Wang J-S, Lin L-D. The Effect of Implant Design and Bone Quality on Insertion Torque, Resonance Frequency Analysis, and Insertion Energy During Implant Placement in Low or Low- to Medium-Density Bone. Int J Prosthodont 2015;28(1):40–7.
66. Wilson TG Jr, Miller RJ, Trushkowsky R, Dard M. Tapered Implants in Dentistry: Revitalizing Concepts with Technology: A Review. Adv Dent Res. 2016 Mar;28(1):4-9.

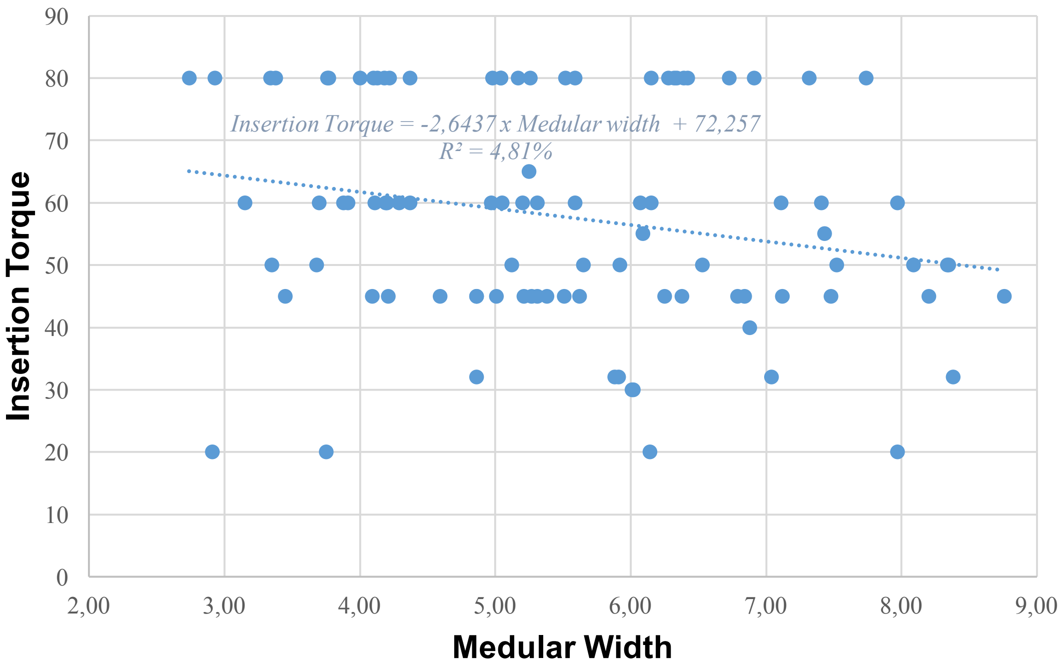
Supplementary material

SM1. Data related to insertion torque studies

S1. The dispersion diagrams related to Insertion Torque and bone characteristics







Insertion Torque = -2,6437 x Medular width + 72,257
R² = 4,81%
Insertion Torque
Medular Width
0
10
20
30
40
50
60
70
80
90
2,00
3,00
4,00
5,00
6,00
7,00
8,00
9,00

SM2. Data related to evaluation of the longitudinal clinical variables

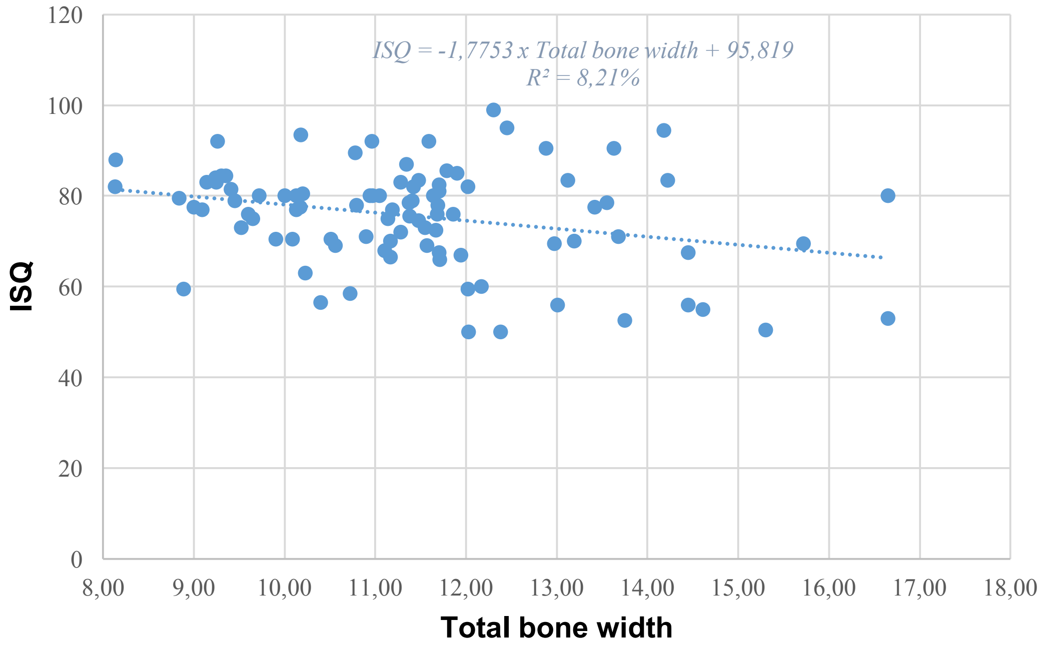
Table S1. One-way ANOVA results for the insertion torque (IT) and repeated measures ANOVAs for the implant stability (ISQ), Visible Plaque Index (VPI) and Degree of Peri-implant inflammation (PI).

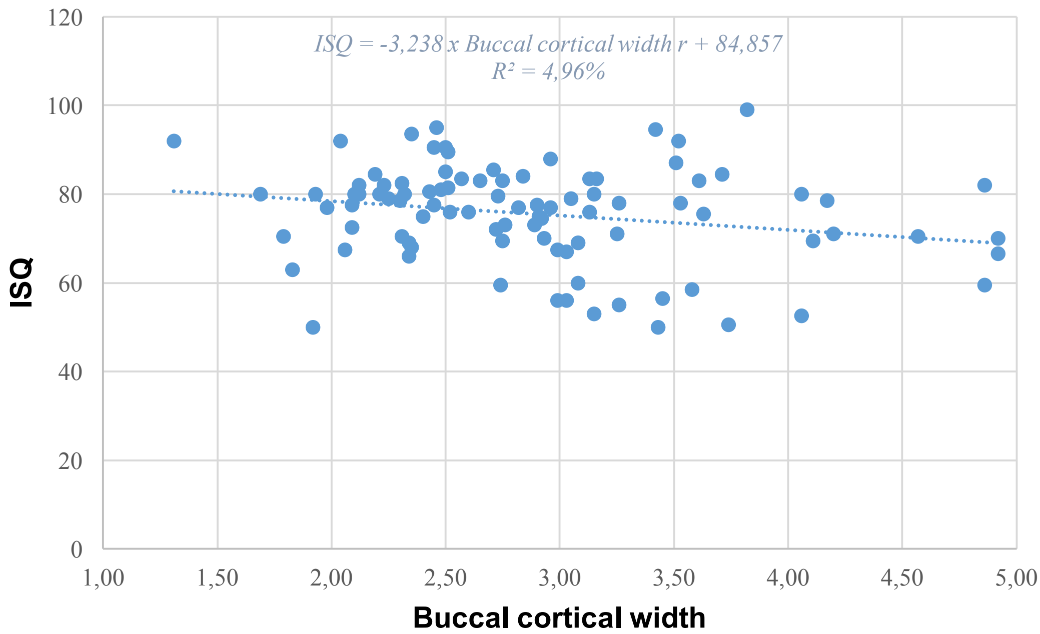
Variable / Effects	**Degrees of Freedom**		**F test**	
	numerator	denominator	F value	p-value
Insertion torque (IT)	3	93	0.33	0.8061
Implant Stability Quotient (ISQ)				
Implant type	3	90	0.70	0.5519
Time	6	507	50.56	**0.0001**
Implant type * Time	18	507	1.16	0.2917
Visible Plaque Index (VPI)				
Implant type	3	88	2.52	0.0633
Time	4	340	31.01	**0.0001**
Implant type * Time	12	340	1.90	**0.0328**
Degree of Peri-implant inflammation (PI)				
Implant type	3	88	0.96	0.4164
Time	4	340	84.00	**0.0001**
Implant type * Time	12	340	0.73	0.7206

Table S2. Mean (standard deviation) for the implant stability quotient (ISQ) during the 3-month follow-up time according to the implants macrogeometry.

	Integra	Duo	Compact	Infra
0 days	72.62(15.38)	76.08(14.33)	75.5(8.97)	76.13(7.52)
7 days	68.36(14.62)	71.65(15.15)	75(7.37)	72.6(8.06)
14 days	72.96(13.54)	77.85(8.82)	72.91(9.02)	71.88(7.93)
21 days	74.42(8.73)	78.73(8.02)	73.82(6.99)	73.52(6.36)
42 days	74.11(11.72)	78.96(6.64)	73.86(5.91)	71.75(5.03)
60 days	75.3(9.91)	77.5(9.52)	73.34(6.56)	71.69(5.47)
90 days	79.08(6.73)	80.58(6.91)	74.8(4.69)	72.33(4.66)

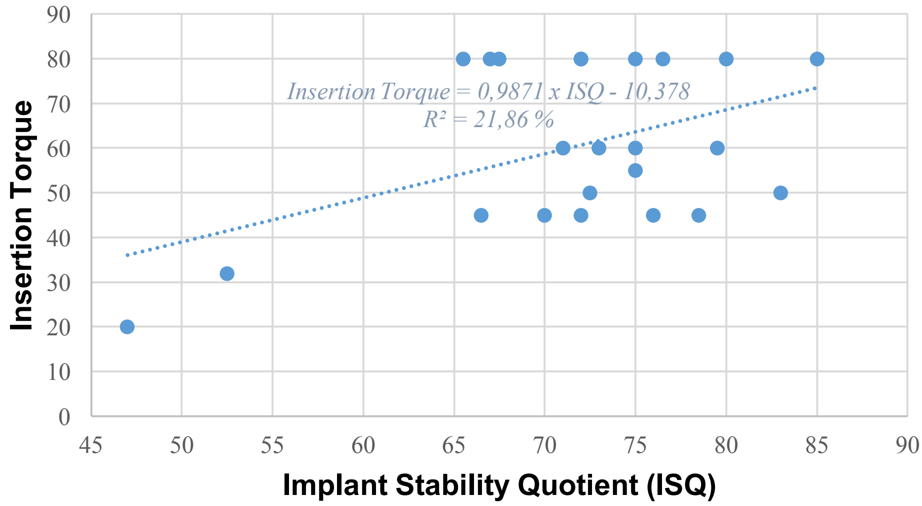
S2. The dispersion diagrams related to Implant Stability Quotient (ISQ) and bone characteristics



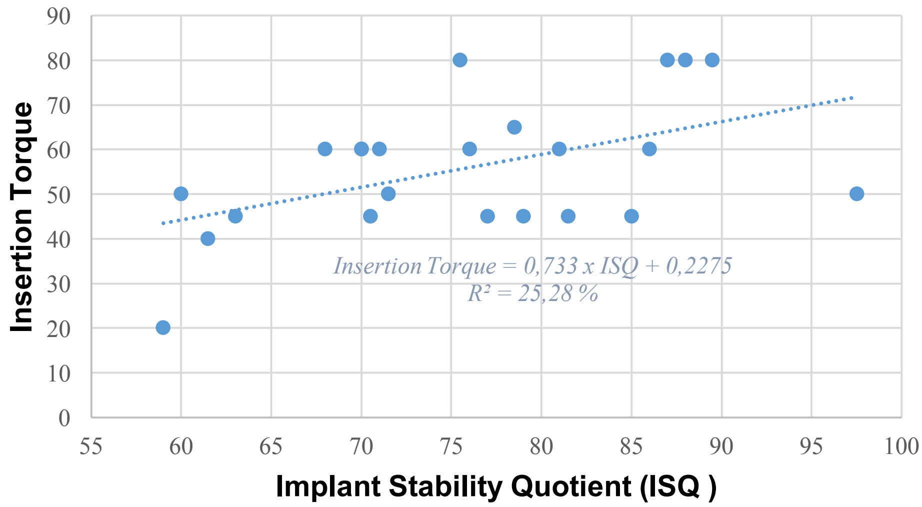


S2. The dispersion diagrams related to Insertion Torque ans Implant Stability Quotient (ISQ)

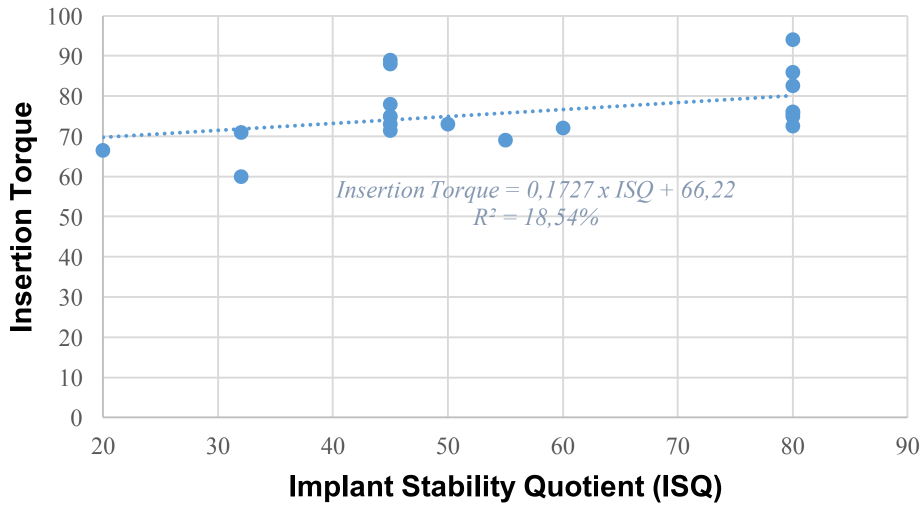
INTEGRA



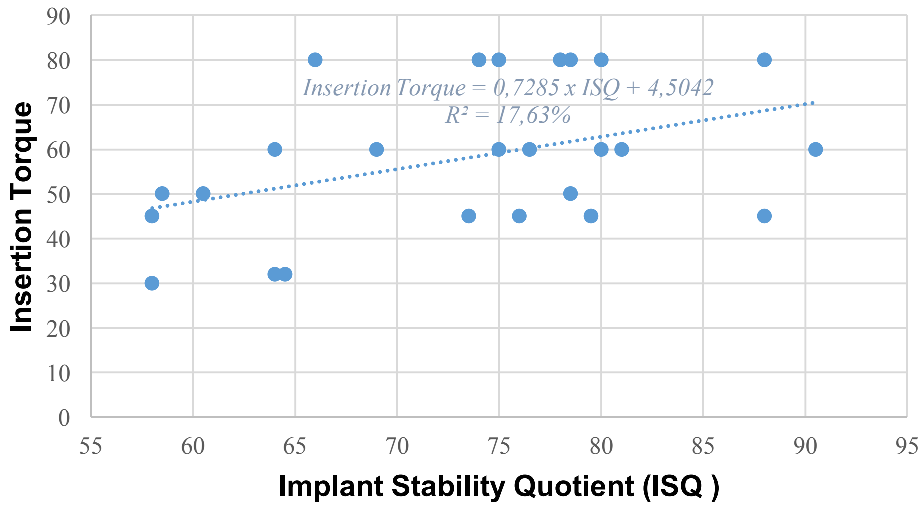
DUO



Compact


Insertion Torque
Implant Stability Quotient (ISQ)
Insertion Torque = 0,1727 x ISQ + 66,22
R² = 18,54%

Infra


Insertion Torque
Implant Stability Quotient (ISQ)
Insertion Torque = 0,7285 x ISQ + 4,5042
R² = 17,63%

3 CONCLUSÃO

As quatro macrogeometrias de implante estudadas não afetaram a estabilidade primária nem a saúde peri-implantar durante o período de cicatrização de 90 dias. No entanto, a macrogeometria do implante influenciou significativamente o início da estabilidade secundária, com grandes diferenças aos 7 e 14 dias.

REFERENCIAS

Bashutski JD, D'Silva NJ, Wang H-L. Implant compression necrosis: current understanding and case report. J Periodontol 2009;80(4):700–4.

Berglundh T, Abrahamsson I, Lang NP, Lindhe J. De novo alveolar bone formation adjacent to endosseous implants: A model study in the dog. Clin Oral Implants Res 2003;14(3):251–62.

Branemark PI, Adell R, Breine U, Hansson BO, Lindstrom J, Ohlsson A. Intra-osseous anchorage of dental prostheses. I. Experimental studies. Scand J Plast Reconstr Surg SWEDEN; 1969;3(2):81–100.

Chapurlat RD, Delmas PD. Bone microdamage: A clinical perspective. Osteoporos Int 2009;20(8):1299–308.

Chowdhary R, Halldin A, Jimbo R, Wennerberg A. Influence of Micro Threads Alteration on Osseointegration and Primary Stability of Implants: An FEA and In Vivo Analysis in Rabbits. Clin Implant Dent Relat Res 2013;562–9.

Coelho PG, Granato R, Marin C, Teixeira HS, Suzuki M, Valverde GB, et al. The effect of different implant macrogeometries and surface treatment in early biomechanical fixation: An experimental study in dogs. J Mech Behav Biomed Mater 2011; 4(8):1974–81.

Coelho PG, Jimbo R. Osseointegration of metallic devices: current trends based on implant hardware design. Arch Biochem Biophys. 2014 Nov; 561:99–108.

Coelho PG, Suzuki M, Guimaraes MVM, Marin C, Granato R, Gil JN, et al. Early bone healing around different implant bulk designs and surgical techniques: A study in dogs. Clin Implant Dent Relat Res 2010 Sep;12(3):202–8.

Coelho PG, Jimbo R, Tovar N, Bonfante EA. Osseointegration: hierarchical designing encompassing the macrometer, micrometer, and nanometer length scales. Dent Mater 2015 Jan;31(1):37–52. a

Coelho PG, Suzuki M, Marin C, Granato R, Gil LF, Tovar N, et al. Osseointegration of Plateau Root Form Implants: Unique Healing Pathway Leading to Haversian-Like Long-Term Morphology. Adv Exp Med Biol 2015;881:111–28. b

De Bruyn H, Van de Velde T, Collaert B. Immediate functional loading of TiOblast dental implants in full-arch edentulous mandibles: a 3-year prospective study. Clin Oral Implants Res 2008 Jul;19(7):717–23.

Donahue SW, Galley S a. Microdamage in bone: implications for fracture, repair, remodeling, and adaptation. Crit Rev Biomed Eng 2006; 34(3):215–71.

Freitas AC, Bonfante EA, Giro G, Janal MN, Coelho PG. The effect of implant design on insertion torque and immediate micromotion. Clin Oral Implants Res 2012;23(1):113–8.

Freitas ACJ, Bonfante EA, Giro G, Janal MN, Coelho PG. The effect of implant design on insertion torque and immediate micromotion. Clin Oral Implants Res 2012 Jan;23(1):113–8.

Gottlow J, Barkamo S, Sennerby L. An Experimental Comparison of Two Different Clinically Used Implant Designs and Surfaces. Clin Implant Dent Relat Res 2012;14(SUPPL. 1):204–12.

Halldin A, Jimbo R, Johansson CB, Wennerberg A, Jacobsson M, Albrektsson T, et al. The effect of static bone strain on implant stability and bone remodeling. Bone 2011;49(4):783–9.

Huang HL, Chang YY, Lin DJ, Li YF, Chen KT, Hsu JT. Initial stability and bone strain evaluation of the immediately loaded dental implant: An in vitro model study. Clin Oral Implants Res 2011;22(7):691–8.

Isidor F. Influence of Forces on Bone Osseo. Clin Oral Implants Res 2006;17(Suppl.2):8–18.

Jimbo R, Janal MN, Marin C, Giro G, Tovar N, Coelho PG. The effect of implant diameter on osseointegration utilizing simplified drilling protocols. Clin Oral Implants Res 2014;25(11):1295–300.

Jimbo R, Tovar N, Anchieta RB, Machado LS, Marin C, Teixeira HS, et al. The combined effects of undersized drilling and implant macrogeometry on bone healing around dental implants: an experimental study. Int J Oral Maxillofac Surg 2014 Oct;43(10):1269–75.

Kim JJ, Lee DW, Kim CK, Park KH, Moon IS. Effect of conical configuration of fixture on the maintenance of marginal bone level: Preliminary results at 1 year of function. Clin Oral Implants Res 2010;21(4):439–44.

Lang NP, Salvi GE, Huynh-Ba G, Ivanovski S, Donos N, Bosshardt DD. Early osseointegration to hydrophilic and hydrophobic implant surfaces in humans. Clin Oral Implants Res 2011;22(4):349–56.

Lee DW, Choi YS, Park KH, Kim CS, Moon IS. Effect of microthread on the maintenance of marginal bone level: A 3-year prospective study. Clin Oral Implants Res 2007;18(4):465–70.

Leonard G, Coelho P, Polyzois I, Stassen L, Claffey N. A study of the bone healing kinetics of plateau versus screw root design titanium dental implants. Clin Oral Implants Res. Denmark; 2009 Mar;20(3):232–9.

Li H, Liang Y, Zheng Q. Meta-Analysis of Correlations Between Marginal Bone Resorption and High Insertion Torque of Dental Implants. Int J Oral Maxillofac Implants 2015;30(4):767–72.

Marin C, Granato R, Suzuki M, Gil JN, Janal MN, Coelho PG. Histomorphologic and histomorphometric evaluation of various endosseous implant healing chamber configurations at early implantation times: a study in dogs. Clin Oral Implants Res 2010 Jun;21(6):577–83.

Nishimura I. Genetic networks in osseointegration. J Dent Res [Internet]. 2013;92(12 Suppl):109S – 18S.

Norton M. Primary stability versus viable constraint--a need to redefine. Int J Oral Maxillofac Implants 2013;28(1):19–21.

Petrie CS, Williams JL. Comparative evaluation of implant designs: Influence of diameter, length, and taper on strains in the alveolar crest - A three-dimensional finite-element analysis. Clin Oral Implants Res 2005;16(4):486–94.

Qian J, Wennerberg A, Albrektsson T. Reasons for Marginal Bone Loss around Oral Implants. Clin Implant Dent Relat Res 2012;14(6):792–807.

Raghavendra S, Wood MC, Taylor TD, Raghavendra S Taylor TD, WMC, Raghavendra S, Wood MC, et al. Early wound healing around endosseous implants: a review of the literature. Int J Oral Maxillofac Implants 2005;20(3):425–31.

Schroeder A, Pohler O, Sutter F. [Tissue reaction to an implant of a titanium hollow cylinder with a titanium surface spray layer]. SSO Schweiz Monatsschr Zahnheilkd SWITZERLAND; 1976 Jul;86(7):713–27.

Shanbhag S, Shanbhag V, Stavropoulos A. Genomic analyses of early peri-implant bone healing in humans: a systematic review. Int J Implant Dent. 2015;1(5):1–12.

Shemtov-Yona K, Rittel D. An Overview of the Mechanical Integrity of Dental Implants. Biomed Res Int 2015; 2015:2–10.

Terheyden H, Lang NP, Bierbaum S, Stadlinger B. Osseointegration--communication of cells. Clin Oral Implants Res. Denmark; 2012 Oct;23(10):1127–35.

Torcato LB, Pellizzer EP, Verri FR, Falcón-Antenucci RM, Santiago Júnior JF, de Faria Almeida DA. Influence of parafunctional loading and prosthetic connection on stress distribution: a 3D finite element analysis. J Prosthet Dent. 2015 Nov;114(5):644-51.

Trindade R, Albrektsson T, Tengvall P, Wennerberg A. Foreign Body Reaction to Biomaterials: On Mechanisms for Buildup and Breakdown of Osseointegration. Clin Implant Dent Relat Res 2016 Feb; 18 (1): 192-203

Vandeweghe S, Nicolopoulos C, Thevissen E, Jimbo R, Wennerberg A, De Bruyn H. Immediate loading of screw-retained all-ceramic crowns in immediate versus delayed single implant placement. Int J Prosthodont 2013;26(5):458–64.

Wang T-M, Lee M-S, Wang J-S, Lin L-D. The Effect of Implant Design and Bone Quality on Insertion Torque, Resonance Frequency Analysis, and Insertion Energy During Implant Placement in Low or Low- to Medium-Density Bone. Int J Prosthodont 2015;28(1):40–7.

Barone A, Alfonsi F, Derchi G, Tonelli P, Toti P, Marchionni S, Covani U. The Effect of Insertion Torque on the Clinical Outcome of Single Implants: A Randomized Clinical Trial. Clin Implant Dent Relat Res. 2016 Jun;18(3):588-600.

ANEXO 1

CERTIFICADO DO COMITÊ DE ÉTICA – PARECER FINAL

FACULDADE DE ODONTOLOGIA DA UNIVERSIDADE FEDERAL DE

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Macrogeometria de implantes e tipo de conexão protética: efeitos sobre a integridade dos tecidos peri-implantares

Pesquisador: Fernanda Faot

Área Temática:

Versão: 2

CAAE: 50263015.4.0000.5318

Instituição Proponente: Faculdade de Odontologia da Universidade Federal de Pelotas/ FO-UFPel

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.468.507

Apresentação do Projeto:

Diferentes desenhos de implante podem gerar diferentes concentrações de tensão e deformação no osso. Informações clínicas sobre a influência desses parâmetros no comportamento do implante e do osso periimplantar ainda são escassas no que se refere a dinâmica de remodelação óssea pós carregamento oclusal. O objetivo desse estudo clínico randomizado, e de boca-dividida será avaliar clinicamente a resposta biológica, a estabilidade secundária e a perda óssea peri-implantar de implantes com macrogeometrais e conexões protéticas diferentes na região posterior de mandíbula no primeiro ano de reabilitação protética. Adicionalmente, o impacto na vida diária destes pacientes após a reabilitação serão avaliadas. Pacientes selecionados para fazerem parte deste estudo deverão ter pelo menos 2 ausências dentárias posteriores, em diferentes hemi-arcos mandibulares. Uma amostra de 25 pacientes será necessária com cálculo amostral baseado em estudos clínicos longitudinais prévios com objetivo similar.-estudos clínicos da CONSORT Standard (Normas Consolidadas do ReportingTrials) (SCHULZ; ALTMAN; MOHER, 2011). Os pacientes com necessidades de reabilitação por ausência de dentes posteriores serão recrutados na Faculdade de Odontologia da Universidade Federal de Pelotas, independente do setor que forem recrutados.

Endereço: Rua Gonçalves Chaves, 457
Bairro: Centro **CEP:** 96.015-560
UF: RS **Município:** PELOTAS
Telefone: (53)3222-4439 **Fax:** (53)3222-4439 **E-mail:** cep.fop@gmail.com

Objetivo da Pesquisa:

Objetivo Geral: Avaliar clinicamente o comportamento biológico, a estabilidade secundária e a perda óssea peri-implantar de implantes de macrogeometrias diferentes (hexágono externo e cone morse) instalados na região posterior de mandíbula no primeiro ano de reabilitação protética. Objetivos Específicos: Monitorar o processo saúde e doença dos tecidos peri-implantares de implantes com diferentes macrogeometria em região posterior de mandíbula, até 12 meses pós reabilitação protética através de indicadores clínicos e radiológicos; Acompanhar o processo de osseointegração por meio da avaliação da estabilidade dos implantes e da quantificação de citocinas pro-inflamatórias coletadas do fluído peri-implantar aos 7, 14, 21, 42, 60 e 90 dias após a osseointegração; Acompanhar a saúde dos tecidos peri-implantares através da quantificação de citocinas pro-inflamatórias coletas do fluído peri-implantar , de exames radiográficos e estabilidade secundária dos implantes aos 3, 6, 9, e 12 meses após a instalação de próteses; Avaliar a relação entre perda óssea e força mastigatória pós reabilitação protética de implantes de macrogeometria cônica e cilíndrica na região posterior da mandíbula; Avaliar a percepção do paciente em relação a reabilitação oral antes e após a instalação dos implantes por meio de questionário relacionado ao impacto na vida diária (DIDL).

Avaliação dos Riscos e Benefícios:

Avaliação dos Riscos e Benefícios: Os riscos são inerentes à terapêutica clínica de instalação dos implantes, como parestesia, não osseointegração ou perda dos implantes, o que ocorre em menos de 3% dos casos. Não há riscos inerentes ao uso de prótese fixa sobre implante. Diante da perda de algum implante, o mesmo será substituído por um novo. Desconforto pode ocorrer durante e após o procedimento operatório, como inchaço e leve sintomatologia na região operada, e desconforto durante a alimentação. Cuidados no pós-operatório serão orientados e entregues por escrito ao paciente para evitar sangramentos ou dor. Também não existe risco previsível durante o exame clínico e as avaliações previstas de seus implantes osseointegrados. Além disso, o tratamento odontológico geral e protético que irão receber é idêntico àqueles que estariam recebendo se não fizesse parte da pesquisa. Benefícios e vantagens ao voluntário: terá o benefício de receber o diagnóstico e tratamento odontológico geral necessário, e também a colocação de dois implantes de cada lado do seu arco mandibular (inferior) com reabilitação protética a fim de devolver uma mastigação mais efetiva e qualidade de vida. A cada consulta o paciente terá o acompanhamento e aconselhamento para a manutenção da sua saúde bucal, ou seja, se for identificado falhas da realização da higiene bucal será executada pelo cirurgião dentista a limpeza e a instrução para adequação da sua técnica de higiene, caso seja identificado algum indício de doença bucal o mesmo será tratado. Assim o tratamento odontológico geral, bem como o seu tratamento protético serão realizados pelos pesquisadores responsáveis. Como benefícios da pesquisa a geração de novos conhecimentos do comportamento biológico de dois modelos de implantes dentários

Comentários e Considerações sobre a Pesquisa:

Projeto bem escrito, pesquisa relevante e bem delineada. As consultas para avaliações clínicas serão realizadas após 7, 14, 21, 42, 60 e 90 dias da instalação dos implantes. Após o período de 1 ano de estudo, os pacientes seguirão sendo acompanhados a cada 6 meses.

Todas as alterações solicitadas no parecer nº 1.328.187 foram atendidas de forma adequada na versão reapresentada.

Considerações sobre os Termos de apresentação obrigatória:

Todos apresentados de forma adequada.

Recomendações:

Nenhuma

Conclusões ou Pendências e Lista de Inadequações:

Nenhuma

Considerações Finais a critério do CEP:

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_569474.pdf	13/03/2016 23:35:07		Aceito
Outros	Cartaesclarecimento14_03_16.pdf	13/03/2016 23:33:38	Fernanda Faot	Aceito
Projeto Detalhado / Brochura Investigador	ProjetoCEPversaorevisada_14032016.docx	13/03/2016 23:28:50	Fernanda Faot	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_novaversao14032016.docx	13/03/2016 23:26:03	Fernanda Faot	Aceito
Outros	Cartaapresentacao.pdf	12/10/2015 21:14:39	Fernanda Faot	Aceito
TCLE / Termos de Assentimento / Justificativa de	TCLE.docx	12/10/2015 21:13:08	Fernanda Faot	Aceito

Ausência	TCLE.docx	12/10/2015 21:13:08	Fernanda Faot	Aceito
Declaração de Instituição e Infraestrutura	Termoresponsabilidadeinstitucional.pdf	12/10/2015 21:08:21	Fernanda Faot	Aceito
Projeto Detalhado / Brochura Investigador	ProjetoCEP.docx	12/10/2015 21:07:52	Fernanda Faot	Aceito
Folha de Rosto	FolhaRosto.pdf	12/10/2015 21:06:25	Fernanda Faot	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

PELOTAS, 29 de Março de 2016

Assinado por:
Renato Waldemarin
(Coordenador)

Endereço: Rua Gonçalves Chaves, 457
Bairro: Centro **CEP:** 96.015-560
UF: RS **Município:** PELOTAS
Telefone: (53)3222-4439 **Fax:** (53)3222-4439 **E-mail:** cep.fop@gmail.com

COMPROVANTE DE SUBMISSÃO DO ARTIGO

Clinical Oral Implants Research

Home

Author

Review

Submission Confirmation

Print

Thank you for your submission

Submitted to
Clinical Oral Implants Research

Manuscript ID
COIR-Mar-17-OR-6119

Title
The effect of implant macrogeometry on peri-implant healing outcomes: a randomized, controlled, split-mouth clinical study

Authors
Carmo-Filho, Luiz
Faot, Fernanda
Bordin, Dimorvan
Madruga, Marina
Del Bel Cury, Altair

Date Submitted
02-Mar-2017

Author Dashboard